IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL, SRL, and ORTHO-MCNEIL, INC., Plaintiffs/Counterclaim-defendants, v. PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC., Defendants/Counterclaim-plaintiffs.	C.A. No. 07-255-JJF (CONSOLIDATED)

DECLARATION OF REETA K. WHITNEY IN SUPPORT OF PLAINTIFFS' MOTION TO STRIKE DEFENDANTS' EXPERT REPORT OF HARRY F. MANBECK, JR.

I, Reeta K. Whitney, declare as follows:

1. I am an associate at the firm of Ropes & Gray LLP. I am resident in Ropes & Gray's Palo Alto office, which is located at 525 University Avenue, Palo Alto, California 94301. Ropes & Gray is trial counsel for Plaintiffs Purdue Pharma Products L.P. ("Purdue") and Napp Pharmaceutical Group Ltd. ("Napp") in this action.

2. I make the following declaration in support of Plaintiffs' Motion to Strike Defendants' Expert Report of Harry F. Manbeck, Jr.

3. Attached as Exhibit A are true and correct copies of the Expert Report of Harry F. Manbeck, Jr. and Exhibits 1 and 2 to the report.

4. Attached as Exhibit B is a true and correct copy of Judge Robinson's Standing Orders entitled "Guidelines: Legal Expert Testimony in Patent Cases."

5. Attached as Exhibit C is a true and correct copy of *Ondeo Nalco Co. v. EKA Chemicals., Inc.*, C.A. No. 01-537-SLR (D. Del. Mar. 21, 2003).

6. Attached as Exhibit D is a true and correct copy of *L'Oreal S.A. v. Revlon Consumer Products. Corp.*, C.A. No. 98-424-SLR (D. Del. Feb. 24, 2000).

7. Attached as Exhibit E is a true and correct copy of *Lucas Aerospace, Ltd. v. Unison Industries.*, L.P., C.A. No. 93-525-JJF (D. Del. Mar. 9, 1995).

8. Attached as Exhibit F is an excerpt of the Pretrial Conference transcript from *Thorn EMI North America, Inc. v. Micron Technology, Inc.*, C.A. No. 92-673-RRM (D. Del. Nov. 23, 1993), cover page and pp. 32-34.

9. Attached as Exhibit G is an excerpt of a hearing transcript from *F. Hoffman-LaRoche, Ltd. v. IGEN International Inc.*, C.A. No. 98-318-JJF (D. Del. Oct. 24, 2000), pp. 1, 61-64.

10. Attached as Exhibit H is a true and correct copy of *Corning Inc. v. SRU Biosystems*, C.A. No. 03-633-JJF (D. Del. Nov. 5, 2004).

I declare under penalty of perjury that the forgoing is true and correct.

Dated: August 8, 2008

REETA K. WHITNEY

CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2008, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

Frederick L. Cottrell, III, Esquire
Steven J. Fineman, Esquire
RICHARDS, LAYTON & FINGER, P.A.

Richard D. Kirk, Esquire
BAYARD, P.A.

Mary W. Bourke, Esquire
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I further certify that I caused to be served copies of the foregoing document on August 8, 2008, upon the following in the manner indicated:

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/s/ Rodger D. Smith II

Rodger D. Smith II (#3778)

EXHIBIT A

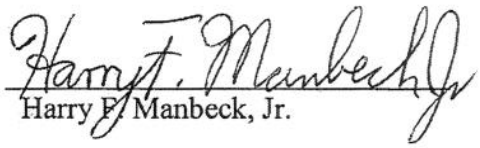
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., BIOVAIL LABORATORIES INTERNATIONAL SRL, and ORTHO-MCNEIL, INC.,	:	
Plaintiffs,	:	**C.A. No. 07-255-JJF (CONSOLIDATED)**
v.	:	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	:	**HIGHLY CONFIDENTIAL PURSUANT TO PROTECTIVE ORDER**
Defendants.	:	

EXPERT REPORT OF HARRY F. MANBECK, JR.

July 24, 2008

Respectfully submitted,



Harry F. Manbeck, Jr.

I. Introduction

1. I have been retained by counsel to Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. ("Par") as an expert in U.S. patent practice and procedures including those at the U.S. Patent and Trademark Office. I may provide testimony in the area of, but not limited to, inequitable conduct. In addition, I may provide testimony in rebuttal to Plaintiffs' expert or fact witnesses.

2. I am an attorney-at-law and a former Commissioner of Patents and Trademarks of the United States. I am registered to practice in the District of Columbia and other jurisdictions and before the United States Patent and Trademark Office (the "PTO"). I am currently a member of the law firm of Rothwell, Figg, Ernst & Manbeck with offices at Suite 800, 1425 K Street, N.W., Washington, DC 20004. Prior to becoming Commissioner, I practiced patent law as an attorney for about thirty-five years and for the last twenty of those years, 1970 to 1990, I was General Patent Counsel for the General Electric Company. Since leaving government service, I have continued in the practice of patent law, specializing in litigation consulting and counseling. My biography and a list of my publications are attached as Exhibits 1 and 2, respectively.

3. As General Patent Counsel of General Electric and in my other employment, including government service, I have had extensive experience in patent practice and procedures. In particular, I have considerable expertise in the analysis of patents and the circumstances pertaining to patents as they may affect issues of patent infringement, validity and unenforceability. My positions at General Electric involved the review and analysis of situations both when General Electric was the patent owner and when it was faced with the patents of others, and involving a wide range of technologies. In my present practice, I have also been

called on from time to time to evaluate and offer opinions as to various patent issues, including questions of patent infringement, validity and enforceability.

4. I reserve the right to revise or supplement my opinions as additional information becomes available. For example, I may respond to matters and opinions raised by Plaintiffs' experts, or matters raised by information Plaintiffs have not yet provided. Exhibits to be used in support of the opinions stated in this report include all of the materials cited in or accompanying this report. Additional demonstrative exhibits based upon this same information may be prepared for trial and used to support my opinions.

II. Compensation and Prior Testimony

5. My consulting fee is $700.00 per hour. No part of my compensation is dependent upon the outcome of this litigation. In the last four years, I have presented deposition, court or arbitration testimony as an expert in the cases listed in Exhibit 3.

III. Materials Considered

6. I have reviewed the '887 patent and the '430 patent, and their respective prosecution histories before the Patent Office, as well as the other materials identified herein.

7. The materials which have been made available to me for consideration are listed in Exhibit 4.

IV. Summary of Opinions

- During prosecution of the patents-in-suit, the applicants failed to disclose commonly owned U.S. Patent 5,580,578, and the application from which it issued, U.S. Patent Application Serial No. 08/097,558. The '558 application was co-pending with U.S. Patent No. 6,254,887, which issued from Application Serial No. 08/677,798. In the '798 application, claims similar to the claims pending in the '558 application were rejected by a different Examiner. These rejections were material to the '887 patent and should have been disclosed to the Examiner handling the '558 application. And the '578 patent was material to the prosecution of the '887 and '430 patents because it anticipates and/or renders obvious the claims-in-suit of the '887 and '430 patents.

- During prosecution of the '887 patent, the applicants failed to disclose commonly owned U.S. Patent No. 5,478,577, which was material to the prosecution of the '887 patent.

- During prosecution of the patents-in-suit, the applicants made material misrepresentations and omissions regarding prior art reference EP 147,780 ("the Merck reference"). In spite of requests by the Examiner for identification of the most relevant information, the applicants buried and misrepresented information directly contradicting two declarations submitted to the Patent Office by the applicant during prosecution of the '887 patent. This information was completely omitted during the prosecution of the '430 patent. In addition, during prosecution of the '887 and '430 patents, the applicants failed to disclose additional material information and information that a reasonable examiner would have considered to be important in deciding whether to allow the applications to issue as patents.

- During prosecution of the patents-in-suit, the applicants submitted a third declaration in support of patentability asserting that formulation design of drugs cannot be extrapolated from one to another due to their different properties, but failed to disclose to the Examiner that hydromorphone has the same water solubility as tramadol. A reasonable examiner would have considered that information to be important in deciding whether to allow the applications to issue as patents in light of prior art describing controlled release formulations of hydromorphone.

V. General Overview of the Patent Prosecution Process

A. The Role of the Patent Office in the United States

8. I may testify generally about the role of the Patent Office in the United States patent system.

9. The Patent Office's mission is to carry out laws passed by Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." (U.S. Const. Art. 1 §8, cl. 8). The PTO does so by implementing the laws as set forth by Congress and as interpreted by the federal courts ("the Patent Laws").

10. The policies of the Patent Office are set forth in Title 37 of the Code of Federal Regulations and the MPEP. The MPEP is the guide pursuant to which Patent Office Examiners conduct the patent examination process. A reasonable PTO Examiner follows the MPEP.

B. The United States Patenting Process

1. Prosecuting a Patent Application

11. The process for applying for a U.S. patent application is a government administrative process. The laws and regulations of 35 U.S.C. §§ 1 *et seq.* and 37 C.F.R. §§ *et seq.*, as interpreted by the Federal courts, govern that process.

12. The U.S. patenting process today is generally the same as the process that was in place during the prosecution of the patents-in-suit. During the relevant period for purposes of this report, the mid 1990's to the mid 2000's, an applicant for a patent first had to file a patent application with the Patent Office. When a patent application was filed with the Patent Office, it was classified based on its technology and sent to an appropriate examining group. The

application was assigned to a Patent Examiner within that group who had the appropriate education and experience in the field of art to which the patent application was directed. The Examiner then reviewed the application for compliance with the statutory requirements for patentability.

13. After reviewing the application and searching the Patent Office files for prior art relating to the claimed invention, the Examiner made a determination whether the pending application complied with the legal requirements for patentability, including enablement and non-obviousness. After reviewing and examining the application, the Examiner then notified the applicant in writing of the Examiner's determination. The Examiner could allow all the claims of the application as originally presented or as amended by the applicant. This would result in the Examiner issuing a Notice of Allowability. The Examiner could also reject some or all of the claims on any number of grounds, including obviousness in light of the prior art. This would result in the Examiner issuing a written communication known as an "Office Action."

14. A rejection by the Examiner elicited a response from the patent attorney representing the applicant, upon which the Examiner later commented. In this manner, the Examiner and applicant's attorney engaged in a give-and-take discussion about each side's view of the patentability of the invention claimed in the application. Typically, an Examiner issued a rejection of at least some of the application's claims as originally presented.

15. The reply filed on behalf of the applicant was known as a "Response," or as an "Amendment." In this reply, the prosecuting attorney could "cancel" or "amend" the application's claims, and could include remarks that explained why the claims were patentable.

The remarks provided the Examiner with insight into the relationship between the claimed invention and the prior art cited by the Examiner in rejecting the claims.

16. Upon receipt of the Response, the Examiner reviewed it and any amendments to the claims. If the Examiner agreed that the claims were patentable, the application was allowed to issue as a patent. Otherwise, the Examiner again rejected one or more claims and issued a second Office Action.

17. This back-and-forth dialogue continued until either the Examiner ultimately concluded that the legal requirements for patentability were satisfied, or the Examiner indicated that the rejections were "final." If the Examiner's rejections were made final, the applicant could appeal the Examiner's decision, or the applicant could file a continuation application and further attempt to argue for the allowance of the claims.

2. Duty of Candor

18. All applicants and their representatives owe a duty of candor and good faith to the Patent Office as their patent applications are processed. This duty includes a duty of disclosure which is codified in the Rules of Practice in Patent Cases before the PTO (Title 37 of the United States Code of Federal Regulations, Chapter I, Part I) as "37 CFR 1.56." Section 37 CFR 1.56, often called Rule 56, imposes a duty to disclose material information known to the applicant or his representatives to the patent examiner, and the current version of Rule 56 defines material information as follows:

> [I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> > (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
> >
> > (2) It refutes, or is inconsistent with, a position the applicant takes in:
> >
> > > (i) Opposing an argument of unpatentability relied on by the Office; or
> > >
> > > (ii) Asserting an argument of patentability. 37 C.F.R. § 1.56(b).

19. This rule further specifies that:

> A prima face case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of the evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion, of patentability. (37 C.F.R. § 1.56)

20. This version of Rule 56 took effect in March 1992. Prior to that, there was a different version of the Rule, which, in pertinent part, read as follows:

> All [individuals substantively associated with filing or prosecuting of a patent application] have a duty to disclose to the Office information they are aware or which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue a patent.

21. Although the current or New Rule 56 does not refer to the "'reasonable examiner" standard of the Old Rule 56, that standard may still be applied in litigation even with regard to applications prosecuted after March 1992. The applicability of either standard to post-March

1992 activities has only recently been clarified by the Federal Circuit in *Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006). I have, in view of *Digital Control*, analyzed whether the circumstances pertaining to the prosecution of the patents-in-suit would be material under the Old Rule 56 materiality standard, as well as under the New Rule 56 standard. The New Rule was intended to give more precise guidance to applicants and attorneys than did the Old Rule and in my opinion the standard of the Old Rule properly applied will ordinarily lead to the same results as the standard of the New Rule.

22. The duty of candor is not merely a procedural requirement. In examining a patent application, an Examiner conducts searches for prior art in order to determine whether the claimed invention is novel and non-obvious. The databases for these searches consist primarily of issued U.S. patents and are limited at best to pending applications, publications, and prior uses or sales. Therefore, the Examiners rely heavily on the applicants to provide material information known to them but which the Examiner has not been able to discover on his own. The duty of candor is intended to ensure that the Patent Office has adequate information to judge patentability, including information which may only be known to the applicants.

23. Examiners may also be asked to consider evidence that applicants submit in support of patentability. The Examiners may not be able to independently determine the completeness or accuracy of, such information, and the duty of candor requires the applicants to be forthright and honest in their submission.

VI. The Doctrine of Inequitable Conduct

24. Violations of the duty of candor may give rise to acts of inequitable conduct that may render a patent unenforceable. In order for inequitable conduct to be found, threshold

showings must first be made (by clear and convincing evidence) that: (1) material information was withheld from the Patent Office, material misstatements were made to the Patent Office, or false material information was provided to the Patent Office; and (2) these acts of omission/commission were engaged in with an intent to deceive the Patent Office. *See, e.g. Flex-Rest LLC v Steelcase, Inc.*, 455 F.3d 1351., 1363 (Fed. Cir. 2006); *Board of Education v. American Bioscience, Inc.*, 333 F.3d 1330, 1343 (Fed. Cir. 2003).[1]

25. If the threshold levels of materiality and intent are satisfied, the Court, exercising its discretion, then balances whether the material misrepresentations or omissions in question are sufficiently significant in light of the evidence of intent for a finding of unenforceability. *See Board of Education,* 333 F.3d at 1343. There is an inverse relationship between the materiality and intent needed to render a patent unenforceable. *See Halliburton Co.* v. *Schlumberger Technology Corp.*, 925 F.2d 1435, 1439 (Fed. Cir. 1991). Thus, the greater the materiality of the misrepresentation or omission, the lesser the showing of intent need be. *Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.*, 525 F.3d 1334, 1344 (Fed. Cir. 2008).

VII. Materiality of U.S. Patent Application Serial No. 08/097,558 and Its Corresponding Issued Patent U.S. Patent No. 5,580,578

26. U.S. Patent No. 6,254,887 (Ex. 5, "the '887 patent"), one of the two patents-in-suit, issued on July 3, 2001. The '887 patent issued from U.S. Patent Application Serial No. 08/677,798 ("the '798 application"), which was filed on July 10, 1996. The other patent-in-suit is U.S. Patent No. 7,074,430 (Ex. 6, "the '430 patent"). The '430 patent issued from U.S. Patent Application Serial No. 09/800,204 ("the '204 application"), which was a continuation of the '798

[1] I do not intend to testify about the principles of law or any particular decision, the exposition of the law being the province of the Court. The decisions mentioned herein are intended to provide an understanding of the background to my opinion.

application. Both the '887 patent and the '430 patent were originally assigned to Euro-Celtique, S.A ("Euro-Celtique").

27. Clifford M. Davidson and Robert J. Paradiso were two of the attorneys of record for both the '798 application and the '204 application. The Examiner assigned to the '798 application was Brian M. Burn. The Examiner assigned to the '204 application was Samuel Barts.

28. U.S. Patent Application Serial No. 08/097,558 ("the '558 application") was filed on July 27, 1993. The '558 application issued on December 3, 1996 as U.S. Patent No. 5,580,578 ("the '578 patent"). The '578 patent is assigned on its face to Euro-Celtique and thus it and its application were commonly owned with the '798 application. Mr. Davidson was also the primary attorney of record for the '558 application. The Examiner assigned to the '558 application was Peter F. Kulkosky.

29. The '558 application and the '578 patent are entitled "Controlled Release Formulations Coated with Aqueous Dispersions of Acrylic Polymers."

30. The '558 application and the '578 patent teach "stable solid controlled release formulation[s] having a coating derived from an aqueous dispersion of a hydrophobic acrylic polymer [that] includes a substrate including an active agent," such as tramadol. (Ex. 7, '578 patent, abstract, cl. 40 and 47).

31. The '558 application and the '578 patent further teach that "the oral solid dosage forms of the present invention provide a desired therapeutic effect for about 24 hours." (Ex. 7, '578 patent, col. 5, ll. 12-14).

32. I understand it is the opinion of Par's formulation expert, Dr. Palmieri, that the '578 patent anticipates and/or renders obvious at least claims 1, 3-6, 13, 15-20, 22-27, 29-32 of the '887 patent and claims 1-17 of the '430 patent under 35 U.S.C. § 102(e).

A. Failure To Disclose Co-Pending U.S. Patent Application Serial No. 08/097,558 During Prosecution of the '887 Patent

33. The '798 application was co-pending with the '558 application. The '798 application was filed on July 10, 1996, approximately 5 months before the '558 application issued as the '578 patent on December 3, 1996.

34. At least originally filed claims 42, 45, 48, 52, 55 and 58 of the '558 application are similar to at least originally filed claims 42-45, 49-50, 52-53, 57 and 62-65 of the '798 application.

35. The copending '558 application, I believe, was material to the patentability of the '798 application. Exhibit 8 illustrates the similarity and overlap in subject matter of the originally filed independent claims 42 and 63-65 of the'798 application on one hand and the originally filed and rejected claim 52 of the '558 application on the other hand.

36. Mr. Davidson and Mr. Paradiso failed to disclose the co-pending '558 application to the U.S. Patent Office during prosecution of the '887 patent. The failure to disclose a material copending United States application is a material omission. *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-6 (Fed. Cir. 2003). Section 2001.06(b) of the Manual of Patent Examining Procedure ("MPEP") states that individuals with a duty to disclose information material to patentability have a duty to bring to the attention of the U.S. Patent Office

information within their knowledge as to other copending U.S. applications which are material to patentability of the application in question.

B. Failure to Disclose During Prosecution of the '887 Patent and the '430 Patent Rejections of Similar Claims By a Different Examiner During Prosecution of the '558 Application

37. For the reasons described above, *supra* ¶¶ 33-36, the originally filed claims in the '798 application were similar to the co-pending claims in the '558 application.

38. The originally filed claims of the '558 application were rejected by Examiner Kulkosky under the judicially created doctrine of obviousness-type double patenting over the commonly owned parent patent to the '558 application, U.S. Patent No. 5,286,493 ("the '493 patent"), and rejected as under 35 U.S.C. § 103 as unpatentable over U.S. Patent Nos. 5,068,110; 4,600,645; 5,024,842; and 5,019,397. (Ex. 9, '578 file history, Office Action dated December 16, 1994).

39. In response to these rejections, Mr. Davidson amended the claims to overcome the rejections under 35 U.S.C. § 103 and filed a terminal disclaimer to remove the double patenting rejection. (Ex. 9, '578 file history, Amendment dated March 30, 1995; Letter Re Submission of Terminal Disclaimer dated December 14, 1995). An interview with the Examiner was needed with respect to the rejections under 35 U.S.C. § 103. (Ex. 9, '578 file history, Examiner Interview Summary Record dated December 29, 1995). The Examiner initially adhered to the Section 103 rejections but withdrew the rejections following the interview. (Ex. 9, '578 file history, Office Action dated July 5, 1995; Examiner Interview Summary Record dated December 29, 1995).

40. I believe Examiner Burn could have also properly rejected the claims of the '798 application as obvious for the same reasons Examiner Kulkosky rejected the originally filed claims of the '558 application had Examiner Burn known about the copending '558 application. I have consulted with Par's formulation expert, Dr. Palmieri, to confirm my opinion.

41. The originally filed claims of the '204 application, which issued as the '430 patent, were also similar to the co-pending claims in the '558 application. Exhibit 8 illustrates the similarity and overlap in subject matter of the originally filed independent claims 42 and 63-65 of the'798 application.

42. Mr. Davidson and Mr. Paradiso failed to disclose Examiner Kulkosky's rejections of the originally filed claims of the '558 application to the U.S. Patent Office during prosecution of the '887 patent. In addition, Mr. Davidson and Mr. Paradiso failed to disclose these rejections to the U.S. Patent Office during prosecution of the '430 patent. The failure to disclose a rejection of similar claims in another United States application by a different Examiner is a material omission. *McKesson Information Solutions, Inc. v. Bridge Medical, Inc.*, 487 F.3d 897, 919-24 (Fed. Cir. 2007); *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003).

C. Failure to Disclose the '578 Patent During Prosecution of the '887 Patent

43. The '887 patent was filed July 10, 1996 as a division of U.S. Patent Application Serial No. 08/241,129, filed on May 10, 1994. The '887 patent claims foreign application priority to: (i) DE 4315525, filed May 10, 1993; (ii) GB 9404544, filed March 9, 1994; (iii) GB 9404928, filed March 14, 1994; and (iv) GB 9324045, filed November 23, 1993.

44. I understand that Par contends that the claims in suit are not entitled to the May 10, 1993 priority date of DE 43 15 525. The '558 application on which the '578 patent was issued was filed on July 27, 1993. This means that the '578 patent is prior art to the claims in suit under 35 U.S.C. § 102(e). My opinion is supported by statements made by the applicants during prosecution of the New Zealand patent application, NZ 260 408 (Ex. 10), corresponding to the patents-in-suit. (Ex. 11, NAPP0267588-NAPP0267600).

45. The '578 patent discloses "solid controlled release oral dosage formulation[s]" for various active agents, including opioid analgesics, such as tramadol or salts thereof (Ex. 7, '578 patent, cl. 43, 47). The "oral solid dosage forms [of the '578 patent] provide a desired therapeutic effect for about 24 hours." (Ex. 7, '578 patent, col. 5, ll. 12-14).

46. The formulations of the '578 patent comprise "substrate[s] containing a systemically active therapeutic agent." (Ex. 7, '578 patent, cl. 43). The substrates of the '578 patent may be "tablets, spheroids (or beads), microspheres, seeds, pellets, ion-exchange resins, and other multi-particulate systems." (Ex. 7, '578 patent, col. 5, ll. 61-63).

47. The substrates are coated with a controlled release coating that is water insoluble. (Ex. 7 '578 patent, cl. 43, col. 5, ll. 60-64). The controlled release coatings of the '578 patent are water insoluble. (Ex. 7, '578 patent, col. 7, ll. 37-39).

48. The formulations of the '578 patent have *in vitro* dissolution ranges that fall within the dissolution ranges required by the claims of the '887 patent. (Ex. 7, '578 patent, cl. 43).

49. Exhibit 12 illustrates how the '578 patent teaches each and every claim element of claims 1, 3-6, 13, 15-20, 22-27, 29-32 of the '887 patent.

50. Mr. Davidson and Mr. Paradiso failed to disclose the '578 patent to the U.S. Patent Office during prosecution of the '887 patent. Mr. Davidson and Mr. Paradiso were aware of the materiality of the '578 patent as evidenced by their disclosure of the '578 patent during prosecution of the child of the '887 patent and the other patent-in-suit, U.S. Patent No. 7,074,430 ("the '430 patent") (Ex. 6). (Ex. 13, '430 patent file history at PAR047105). The application for the '430 patent was a continuation of the application for the '887 patent, and nothing in the record of either application indicates that Mr. Davidson and Mr. Paradiso brought to the Examiner's attention that the '578 patent is available as prior art under Section 102(e).

VIII. Materiality of U.S. Patent No. 5,478,577

A. Failure to Disclose U.S. Patent No. 5,478,577 During Prosecution of the '887 Patent

51. U.S. Patent No. 5,478,577 ("the '577 patent") issued December 26, 1995 and is entitled "Method of treating pain by administering 24 hour oral opioid formulations exhibiting rapid rate of initial rise of plasma drug level."

52. As noted above, I understand that Par contends that the claims in suit are not entitled to the May 10, 1993 priority date of DE 43 15 525. The application for the '577 patent was filed on November 23, 1993 and thus is prior to any other priority date available to the claims-in-suit.

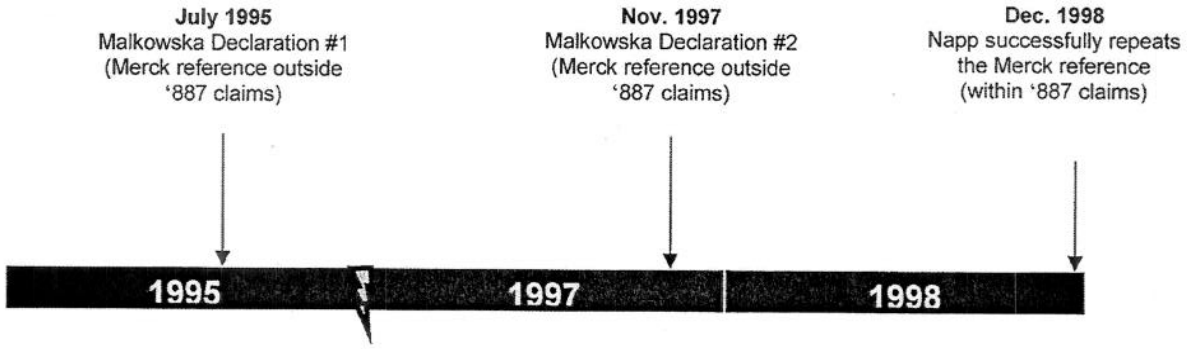
53. The '577 patent teaches oral controlled release formulations of a substrate comprising an active agent, such as tramadol or a salt, coated with a controlled release coating that provide effective pain relief in humans for about 24 hours.

54. I understand it is the opinion of Par's formulation expert, Dr. Palmieri, that the '577 patent anticipates and/or renders obvious at least claims 1, 3-6, 13, 15-20, 22-27, 29-32 of the '887 patent under 35 U.S.C. § 102(e).

55. According to Mr. Davidson's October 22, 1997 declaration, he was principally responsible for the drafting, filing and prosecution of the '577 patent. (Ex. 14, October 22, 1997 Declaration of Clifford M. Davidson, Esquire at PUR1107338).

56. Mr. Davidson, Mr. Paradiso and Mr. Milnes failed to disclose the '577 patent to the U.S. Patent Office during prosecution of the '887 patent. Mr. Davidson and Mr. Paradiso were aware of the materiality of the '577 patent as evidenced by their disclosure of the '577 patent during prosecution of the '430 patent. (Ex. 13, '430 patent file history at PAR047105). Nothing in the record indicates that Mr. Davidson and Mr. Paradiso brought to the Examiner's attention that the '577 patent is available as prior art under Section 102(e).

IX. Materiality of the Merck Reference Experiments By Napp To the Prosecution of the '887 Patent and the '430 Patent



A. Malkowska Declarations Submitted To the European Patent Office In Support Of Patentability Over the Merck Reference

57. European Patent No. 624,366 (Ex. 15, "the European '366 patent") is a foreign counterpart to the patents-in-suit: U.S. Patent No. 6,254,887 (Ex. 5, "the '887 patent") and U.S. Patent No. 7,074,430 (Ex. 6 "the '430 patent").

58. During prosecution of the European '366 patent, the inventors and Napp's in-house patent agent, Rodger Milnes, submitted two declarations by inventor Sandra Malkowska on behalf of Euro-Celtique, a patent holding company for Plaintiffs Purdue and Napp. The two Malkowska declarations concerned the patentability of the alleged invention in view of EP 147,780 (Ex. 16, "the Merck reference" or "the Bondi reference").

59. The first declaration submitted to the European Patent Office in support of patentability was dated July 26, 1995. (Ex. 17, July 26, 1995 Malkowska declaration). In her July 26, 1995 declaration, Ms. Malkowska purported to repeat the preparation and test of controlled release tramadol hydrochloride formulations following the teachings of Example 1 of the Merck reference. *Id.*

60. The Merck reference teaches controlled release oral pharmaceutical preparations for drugs, including tramadol, that employ a polyvinyl alcohol ("PVA") coating of 1% to 15%. (Ex. 16, EP 147,780 at NAPP0045471). The Merck reference further states that a PVA coating of 3% to 10% is preferred. (Ex. 16, EP 147,780 at NAPP0045471).

61. Shortly after the submission of the July 26, 1995 Malkowska declaration, Grünenthal GmbH initiated an opposition to the European '366 patent and was joined by several other opponents.

62. In response to criticisms of the July 26, 1995 Malkowska declaration, Euro-Celtique, Mr. Milnes and the inventors submitted a second declaration by Ms. Malkowska. The second Malkowska declaration was submitted to the European Patent Office in support of patentability on November 19, 1997. (Ex. 18, November 19, 1997 Malkowska declaration). In the November 19, 1997 declaration, Ms. Malkowska purported to repeat the experiments from her July 26, 1995 declaration. *Id.* Ms. Malkowska concluded that tramadol preparations based on the Merck reference "demonstrate no real control of the release of tramadol." *Id.* at 1.

63. The experiments underlying the two Malkowska declarations were supervised by inventor Ms. Malkowska and inventor Dr. Derek Prater. (Ex. 19, Malkowska Tr. 16:22-17:6, 156:11-157:2).

64. The two Malkowska declarations were drafted in part by Mr. Milnes. (Ex. 20, Milnes Tr. 109:11-24; Ex. 19, Malkowska Tr. 16:17-18).

65. Mr. Milnes relied on inventors Malkowska and Prater for the underlying experimental work supporting the two Malkowska declarations. (Ex. 20, Milnes Tr. 133:7-11).

B. Napp Repeat Experiments of the Second Malkowska Declaration Performed During the *Napp v. Asta* U.K. Litigation

66. In 1998, Napp filed an action against Asta Medica Limited ("Asta") in the United Kingdom alleging infringement of the European '366 patent.

67. Napp again relied on the results described in the November 19, 1997 Malkowska declaration during its litigation in the United Kingdom against Asta. (Ex. 21, Napp's Notice of Experiments, Part C(a) at 2, 13-15). Pursuant to U.K. court procedure, the experiments described in the November 19, 1997 Malkowska declaration were repeated at Napp's U.K. facility by Napp employees on December 15-22, 1998 ("Napp repeat experiments"), under the supervision of inventor Derek Allan Prater and in the presence of representatives for Asta. (Ex. 22, Supplemental Expert Report of Napp's Expert Professor Florence, ¶ 8; Ex. 23, Confidential Supplemental Expert's Report of Asta Expert John Tasker Fell, ¶ 11).

68. Napp's expert and Asta's expert both agreed that the repeat experiments gave results that contradicted the Malkowska declarations (Ex 22, Supplemental Expert Report of Professor Florence ¶ 8; Ex. 23, Confidential Supplemental Expert's Report of John Tasker Fell ¶ 12).

69. According to Napp's expert, the results from the repeat experiments "differed from those in the Notice in that the dissolution results fell within those set out in the claims of the Napp patent." (Ex 22, Supplemental Expert Report of Professor Florence ¶ 8).

70. According to Asta's expert, the results from the repeat experiments "demonstrates that the 5% PVA film-coated tablet made by Napp falls squarely within the range of release rates

set out in the [European '366] Patent." (Ex. 23, Confidential Supplemental Expert's Report of John Tasker Fell ¶ 12).

71. The broadest range of release rates set out in the European '366 patent are identical to the broadest range of release rates set out in at least one claim of the '887 patent. (*E.g., compare* Ex. 15, European '366 patent, claim 3 with Ex. 5, '887 patent, claim 1).

72. The results from the Napp repeat experiment "are therefore inconsistent with the pre-litigation experiments conducted by Dr. Malkowska," *i.e.*, her July 26, 1995 and November 19, 1997 declarations. (Ex. 23, Confidential Supplemental Expert's Report of John Tasker Fell ¶ 12).

73. The dissolution data from the Napp repeat experiments fell squarely within claim 1 of the '887 patent and claim 7 of the '430 patent, *infra* ¶ 131.

C. Submission of the Merck Reference Experiments To the U.S. Patent Office

74. During prosecution of the '887 patent, attorneys Clifford M. Davidson and Robert J. Paradiso, acting for the inventors and Euro-Celtique, submitted the July 26, 1995 and the November 19, 1997 Malkowska declarations to the U.S. Patent Office in support of patentability. (Ex. 24, '887 patent file history, Information Disclosure Statements Concerning Related Foreign Litigation dated March 1, 1999 ("the March 1, 1999 IDS") and March 10, 2000 ("the March 10, 2000 IDS")). This submission was approved by Mr. Milnes. (Ex. 20, Milnes Tr. 34:18-38:2).[2]

75. Following Napp's repeat experiments in the U.K. litigation—the results of which contradicted Ms. Malkowska's declarations—Mr. Davidson and Mr. Paradiso represented to the

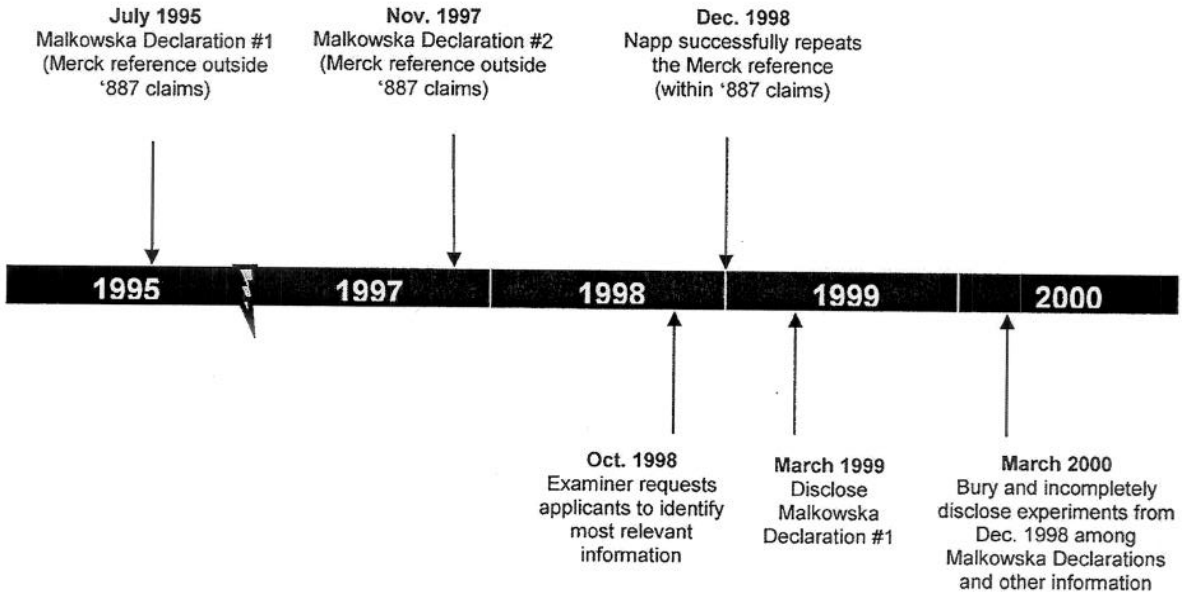
[2] It shall be understood that references herein to acts by attorneys Mr. Davidson and/or Mr. Paradiso were on behalf of the inventors and Euro-Celtique, and with the approval of Mr. Milnes.

U.S. Patent Office that "[a]lthough Asta has taken the position that these experimental results demonstrate that the product prepared according to the disclosure of the Merck reference reads on the product of the corresponding EP granted patent No. 0 624 366 B1, Applicants respectfully submit that the evidence is to the contrary." (Ex. 24, '887 file history at PAR046304, PAR046327). Mr. Davidson and Mr. Paradiso failed to inform the Patent Office that Napp's own expert in the Asta litigation concluded that "the dissolution results [from the Napp repeat experiments] fell within those set out in the claims of the Napp patent [the European '366 patent]." (Ex. 22, Supplemental Expert Report of Professor Florence at DDK0006996).

76. During prosecution of the '430 patent, Mr. Davidson and Mr. Paradiso submitted the July 26, 1995 Malkowska declaration in support of patentability, including substantial portions of the declaration within the text of a response to a Patent Office rejection. (Ex. 13, '430 patent file history at PAR046780-PAR046796). Over 5 years after Napp's repeat experiments in the U.K. litigation—and Napp's own expert's conclusion that the Merck reference provided a composition falling within the claims—Mr. Davidson and Mr. Paradiso represented that the July 26, 1995 Malkowska declaration demonstrated that the Merck reference "d[id] not exhibit or enable 12 to 24 hour controlled release dosage forms." (Ex. 13, '430 patent file history at PAR046789).

D. Material Omissions and Misrepresentations Relating To the Merck Reference Experiments

1. Despite the Examiner's Request To Identify the Most Relevant Information, the submission of the Napp Repeat Experiments and Other Experiments Were Buried Among Inconsistent Information



77. During prosecution of the '887 patent, in an October 27, 1998 Office Action, the U.S. Patent Examiner requested (i) a brief summary of the 129 references provided by the applicants, including their relevance to the pending claims; and (ii) that the applicants "identify those references they deem most material to the claimed invention." (Ex. 24, '887 patent file history at PAR046254).

78. The Examiner warned the applicants that "the courts have held that an applicant may be guilty of inequitable conduct if the applicant is aware that certain references within a large information disclosure statement are more material than the rest and does not inform the PTO as to which references the applicant considers to be most material." (Ex. 24, '887 patent file history at PAR046254). The Examiner further stated that "there has been an additional

burden placed on applicants who submit large volumes of prior art to identify pieces of prior art which are deemed most material by the applicant." The Examiner further stated that it was his "intent, in raising this issue, to ensure that it is adequately addressed during *ex parte* proceedings and therefore could not become an issue after a patent is allowed." (Ex. 24, '887 patent file history at PAR046254).

79. In response, Mr. Davidson and Mr. Paradiso submitted a March 1, 1999 Information Disclosure Statement Concerning Related Foreign Litigation. This IDS was submitted after the Napp repeat experiments from December 1998 the results of which were inconsistent with the Malkowska declarations. (Ex. 24, '887 patent file history at PAR046302-PAR046308). Mr. Davidson and Mr. Paradiso did not contest or object to the Examiner's request that they identify the most relevant documents.

80. In the March 1, 1999 IDS, Mr. Davidson and Mr. Paradiso brought to the Examiner's attention various experiments conducted concerning to the Merck reference, including the July 26, 1995 Malkowska declaration and documents from the *Napp v. Asta* litigation, but did not provide any information concerning Napp's repeat experiment.

81. Mr. Davidson, Mr. Milnes and inventor Prater were aware of the inconsistent results from the Napp repeat experiment. (Ex. 25, Letter from Rowland to Lea dated December 23, 1998; Ex. 26, E-mail from Dyer to Prater dated January 8, 1999).

82. Specifically, Mr. Davidson and Mr. Milnes were informed on December 23, 1998 that "It is necessary that [Napp's U.K. attorneys] have a precise understanding of the reasons for the failure of these experiments." (Ex. 25, Letter from Rowland to Lea dated December 23, 1998 at DDK0014812).

83. The "failure of the experiments" was, as noted in the Supplemental Expert Report of Professor Florence, "that the dissolution results fell within those set out in the claims of the Napp patent." (Ex. 22, Supplemental Expert Report ¶ 8).

84. Inventor Prater was provided "a draft report on the [experiments] undertaken in Cambridge" on January 8, 1999. (Ex. 26, E-mail from Dyer to Prater dated January 8, 1999).

85. No information relating to Napp's inconsistent repeat experiments was brought to the Examiner's attention in the March 1, 1999 IDS. (Ex. 24, '887 patent file history at PAR046302-PAR046308).

86. In the March 1, 1999 IDS, Mr. Davidson and Mr. Paradiso asserted that "Although Asta has taken the position that these experimental results [from the Malkowska declarations] demonstrate that the product prepared according to the disclosure to the Merck reference reads on the product of the corresponding EP granted patent No. 0 624 366 B1, applicants respectfully submit that "the evidence is to the contrary." (Ex. 24, '887 patent file history at PAR046304).

87. In the March 1, 1999 IDS, Mr. Davidson and Mr. Paradiso commented on a Report by Asta's expert, Dr. Helmut Momberger, in the *Napp v. Asta* litigation. Mr. Davidson and Mr. Paradiso stated that two methods (direct compression and precompression) were tested. The Examiner was informed that a formulation based on Example 1 of the Merck reference using PVA coating levels of about 5%, 10% and 15% was produced by precompression, which was an alternative method to direct compression. Mr. Davidson and Mr. Paradiso asserted that "The Momberger product obtained by direct compression and with a loading of 4.9% PVA gives a fast release of the tramadol… It is respectfully submitted that such a product bears no similarity to

the claimed invention, particularly to the dissolution rates set forth in the pending claims." (Ex. 24, '887 patent file history at PAR046303-PAR046306).

88. There was no discussion or mention of the fact that coating levels of 9% and 13% PVA using direct compression fell directly within the '887 patent claims and that coating levels of 10% and 15% PVA using precompression fell directly within the '887 patent claims.

89. In the March 1, 1999 IDS, Mr. Davidson and Mr. Paradiso also asserted that in another Momberger Report from the *Napp v. Asta* litigation, entitled "Report of Repeat Experiment," "[t]he example made with a 5% polyvinyl alcohol [PVA] coating falls outside of the lower limits of the claimed dissolution ranges of the EP patent (and of the pending claims as well)." (Ex. 24, '887 patent file history at PAR46303-PAR046306).

90. There was no discussion or mention of the fact that coating levels of 7.5%, 10%, 12.5% and 15% fell within the claims of the '887 patent. Mr. Davidson and Mr. Paradiso failed to discuss or even mention data contained in the Momberger reports that fell directly within in the claims of the '887 patent.

91. For both reports by Dr. Momberger, Mr. Davidson and Mr. Paradiso selectively summarized Dr. Momberger's *in vitro* dissolution data that allegedly fell outside the claims of the '887 patent.

92. Despite the Examiner's request for the applicants to identify the most material and relevant information, Mr. Davidson and Mr. Paradiso failed to provide the Examiner with a complete and accurate summary of the data from the Momberger reports. They omitted information regarding formulations with PVA coating levels which all fell within the *in vitro*

dissolution ranges set forth in at least claims 1-3, 7, 13-15 and 19 of the '887 patent from their comments. (Ex. 27, Momberger Report at DDK009304, DDK009306; Ex. 28, Momberger Report of Repeat Experiment at DDK010544, DDK010548). This has been confirmed by Par's formulation expert, Dr. Palmieri.

93. A reproduction of the complete set of data provided by the Momberger reports is below:

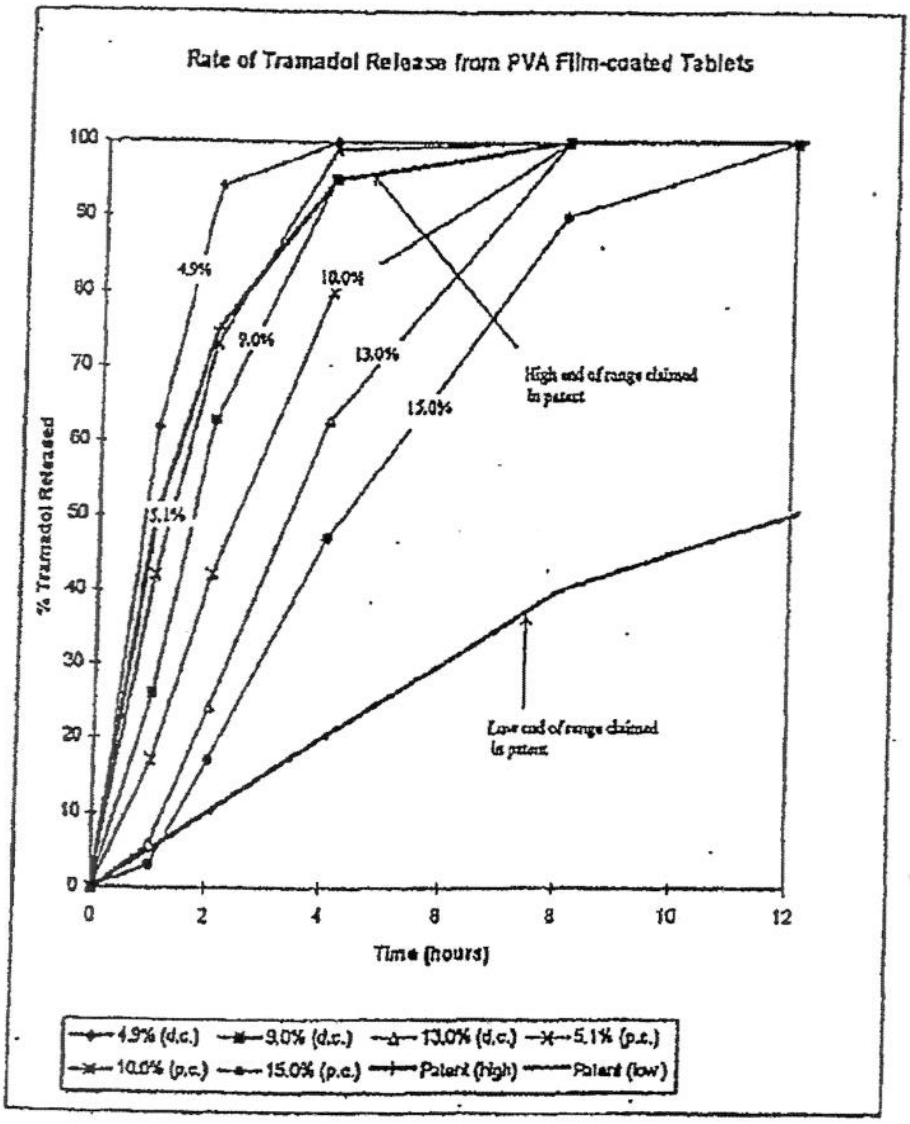
Tablet type	Direct compression			Precompression		
mg Airvol/tablet	18	35	53	19	39	62
% PVA	4.9%	9.0%	13.0%	5.1%	10.0%	15.0%
% Drug release						
After 1hr	62	26	6	42	17	3
2 hrs	94	63	24	73	42	17
4 hrs	101	95	63	99	80	47
8 hrs	102	-	100	104	102	90
12 hrs	102	-	103	104	104	100
18 hrs	-	-	-	-	-	-
24 hrs	101	-	102	103	103	101
% drug released plus residual drug	101	100	102	103	103	101

(Ex. 27, Momberger Report at DDK009304).

mg Airvol/tablet	18.5	28.5	39.1	50.3	62.1
% PVA	5%	7.5%	10%	12.5%	15%
% Drug release					
After 1hr	42.4	28.8	17.8	7.8	3.2
2 hrs	74.4	58.0	41.9	27.2	17.1
4 hrs	97.0	92.0	80.0	64.2	48.0
8 hrs	100.7	100.0	97.5	97.4	89.7
12 hrs	102.0	101.3	100.9	101.6	98.7
18 hrs	-	101.6	100.6	101.3	100.1
24 hrs	-	101.5	100.5	101.7	100.9
% drug released plus residual drug	101.2	101.6	100.7	101.8	101.0

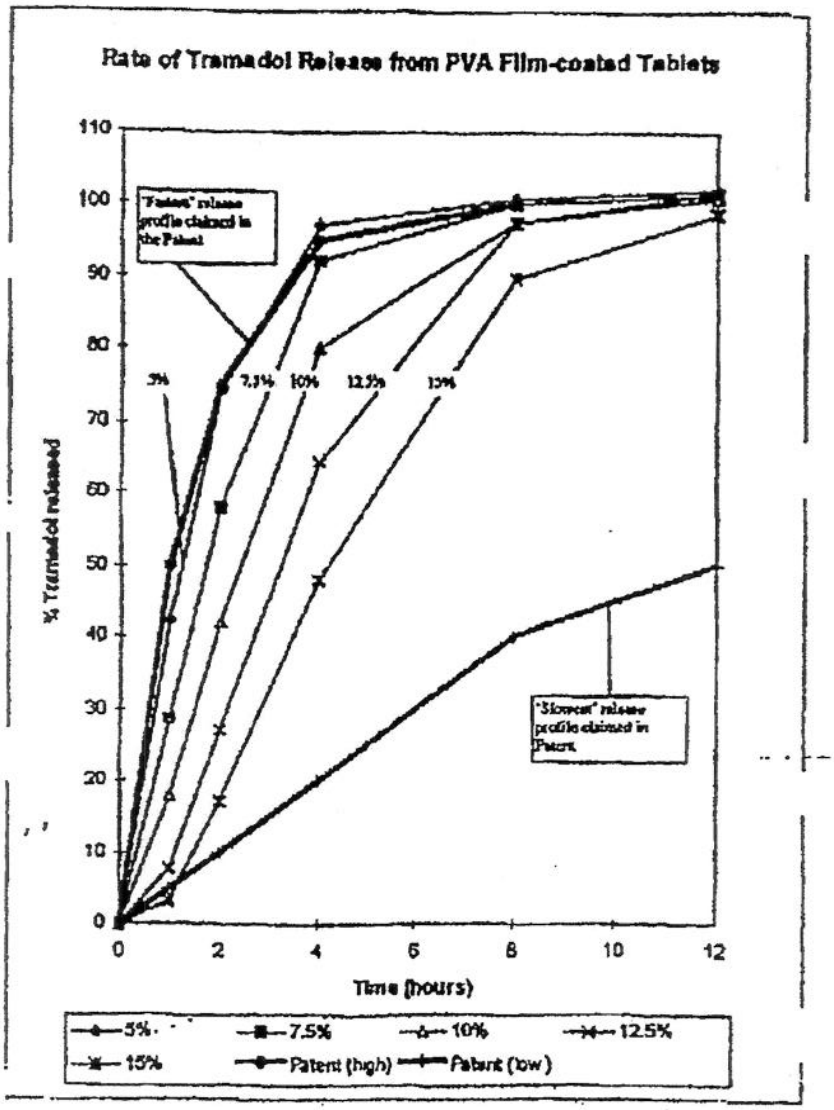
(Ex. 28, Momberger Report of Repeat Experiment at DDK010548).

94. The Momberger reports also provide graphical depiction of the data for all of the PVA coating levels tested:



%'s marked on lines are the % of PVA as a proportion of total tablet weight
d.c. = tablets made by direct compression method
p.c. = tablets made by precompression method

(Ex. 27, Momberger Report at DDK009304).



%'s marked on lines are the % of PVA as a proportion of total composition weight
All tablets made by precompression method

Note: Zero hour points are theoretical
Claim 1 of the Patent does not specify an upper limit for the % of tramadol released after 12 hours

(Ex. 28, Momberger Report of Repeat Experiment at DDK010544).

95. In the March 1, 1999 IDS, Mr. Davidson and Mr. Paradiso further asserted that "the release rates of these tablets [based on Example 1 of the Merck reference] were not in

accordance with those claimed in the European patent EP 0 624,366 B1." (Ex. 24, '887 patent file history at PAR046307).

96. In the March 1, 1999 IDS, Mr. Davidson and Mr. Paradiso concluded that "the experimental evidence presented in accordance with the procedures followed by Asta do not provide formulations which anticipate or render the presently claimed invention obvious." (Ex. 24, '887 patent file history at PAR046307). This conclusion ignores the evidence to the contrary, which was established by the Napp repeat experiments—the evidence which caused Dr. Florence to conclude the results "differed from those in the Notice in that the dissolution results fell within those set out in the claims of the Napp patent" and Napp's counsel to characterize these experiments as a "failure." (Ex. 22, Supplemental Expert Report of Professor Florence ¶ 8).

97. In a March 10, 2000 Information Disclosure Statement Concerning Related Foreign Litigation, Mr. Davidson and Mr. Paradiso resubmitted essentially verbatim the March 1, 1999 IDS followed by an additional approximately 11 single-spaced pages. (Ex. 24, '887 patent file history at PAR046325-PAR0046341).

98. Despite being aware of contradictory information, Mr. Davidson and Mr. Paradiso repeated the following assertions made in the March 1, 1999 IDS:

- "Although Asta has taken the position that these experimental results demonstrate that the product prepared according to the disclosure to the Merck reference reads on the product of the corresponding EP granted patent No. 0 624 366 B1, Applicants respectfully submit that the evidence is to the contrary." (Ex. 24, '887 patent file history, Information Disclosure Statement dated March 10, 2000 at PAR046327).

- "The example made with a 5% polyvinyl alcohol coating falls outside of the lower limits of the claimed dissolution ranges of the EP patent (and of the pending claims as well)." (Ex. 24, '887 patent file history, Information Disclosure Statement dated March 10, 2000 at PAR046329).

- "[T]he release rates of these tablets [based on Example 1 of the Merck reference] were not in accordance with those claimed in the European patent EP 0 624,366 B1." (Ex. 24, '887 patent file history, Information Disclosure Statement dated March 10, 2000 at PAR046329).

These assertions were made regarding the European '366 patent and not the '887 patent.

99. Despite evidence to the contrary (the Napp repeat experiments, *infra* ¶¶ 100-106), Mr. Davidson and Mr. Paradiso also repeated the following assertion regarding the report of Dr. W. Posch, an expert for a third party opposing the European '366 patent (Ex. 29, Posch report at DDK009311-DDK009316 ("the Posch report"):

> However, the Patentee's expert, Professor Alexander Taylor Florence, has pointed out that Dr. Posch made important modifications in the experimental procedure of Example 1 of Merck, including a precompression step (all formulations) and a multi-step, prolonged coating (at least with respect to the formulations having a 9.0% PVA coating). Important deficiencies concerning testing such as that accomplished in Exhibit 14 are set forth in Exhibit 24, the Supplemental Expert Report of Professor Florence.

(Ex. 24, '887 patent file history at PAR046332).

100. On pages 10 and 11 of the March 10, 2000 IDS, a 17 page submission (plus exhibits), Mr. Davidson and Mr. Paradiso finally disclosed the Napp repeat experiments, approximately 15 months after they were conducted.

> As previously brought to the attention of the Examiner, there was a litigation concerning European Patent EP 0 624 366 (Napp Pharmaceutical Group Limited v. Asta Medica Limited).

Which was settled prior to trial. While the litigation was pending, experiments were performed concerning Example 1 of EP 147 780 (Merck; also referred to as "the Merck reference"). Additional (non-confidential) submissions in the UK litigation (which were made available to the firm of the undersigned attorney) relating to the Merck reference are submitted herewith as Exhibits 24-26.

Exhibit 24 is a copy of the Supplemental Expert Report of Professor Florence (submitted by Napp Pharmaceutical Group Limited, an associated company to Euro-Celtique, S.A., the assignee of EP 0624 366). In his Supplemental Report, Professor Florence discusses (a) further experiments conducted under his direction at the London School of Pharmacy on behalf of Napp (the "Construction Experiments"); (b) experiments conducted by Napp relating to the Merck patent (wherein a "matrix" product using polyvinyl alcohol (PVA) was prepared); (c) experiments conducted by Asta relating to a pre-compressed tablet coated with a mixture containing, inter alia, PVA; (d) a repeat of Napp's Merck coated tablet experiment (without precompression), in which the results differed from those in Napp's first experiment, and which dissolution results fell within those set out in the claims of the EP 0 624 366[FN]; and (e) clarifies a statement made in this November 25, 1998 report concerning the percentage of PVA employed in Example 1 of the Merck patent. A copy of Professor Florence's Report of November 25, 1998, is attached hereto as Exhibit 25.

> [FN: Although Professor Florence states that the dissolution results fell within those set forth in the patent-in-suit, he also noted that the tableting machine was changed as compared to the machine used in the original experiment.]

A Supplemental Expert's Report of John Tasker Fell, submitted by Asta and attached hereto as Exhibit 26 (nonconfidential version), further comments on the results of the experiments performed relating to Example 1 of EP 147 780 as part of the repeat experiments and replys [sic] to "certain matters raised by Professor Florence". In his Report, Dr. Fell states that (a) Merck teaches the skilled man how to make controlled release formulations of tramadol which fall within the range of release parameters set out in Claim 1 of the EP 0 624 366 patent; (b) that there is no significant different between using precompression versus direct compression techniques; (c) that "[c]oating over a period of days is perfectly standard for the manufacture of coated tablets" (See Exhibit 26, page 4, paragraph 10); (d) that the repeat experiments performed at Napp provided 5% PVA film-coated

> tablets that fall "squarely within the range of release rates set out in the [EP 0 624 366] patent"; and (e) discusses the use of ethylcellulose as a retardant material as a component of a controlled release formulation.

(Ex. 24, '887 patent file history at PAR04334-046335).

101. Nothing was done to bring the Examiner's attention to the crucial information. For instance, the following information could have been highlighted:

> "**(d) a repeat of Napp's Merck coated tablet experiment (without precompression), in which the results differed from those in Napp's first experiment, and which dissolution results fell within those set out in the claims of the EP 0 624 366**;" and
>
> "**(d) that the repeat experiments performed at Napp provided 5% PVA film-coated tablets that fall "squarely within the range of release rates set out in the [EP 0 624 366] patent"**

(Ex. 24, '887 patent file history at PAR04334-046335 (emphasis added)).

102. It should be noted that when discussing the Napp repeat experiment, Mr. Davidson and Mr. Paradiso did not remind the Examiner that the broadest range of release rates set out in the European '366 patent are identical to the broadest range of release rates set out in the claims of the '887 patent. (*E.g., compare* Ex. 15, European '366 patent, claim 3 with Ex. 5, '887 patent, claim 1). But when asserting patentability over the Merck reference, Mr. Davidson and Mr. Paradiso did make an effort to remind the Examiner that the claims in the European '366 patent and the claims of the '887 patent have common dissolution ranges, *supra*, ¶ 71 ("The example made with a 5% polyvinyl alcohol coating falls outside of the lower limits of the claimed dissolution ranges of the EP patent (**and of the pending claims as well**)." (Ex. 24, '887 patent file history at PAR046329 (emphasis added)).

103. Professor Florence retracted his prior concerns regarding pre-compression having a significant factor in controlling the release of tramadol.

> [In my first report] I also commented in outline upon the experiments that had been carried out by ASTA in which a pre-compressed tablet was coated with a mixture containing, inter alia, PVA. I was concerned that the pre-compression step (which is not described in the Merck patent may be a significant factor in controlling the release of tramadol.
>
> ***
>
> In the [sic] light of these results [of the Napp repeat experiment where the dissolution results fell within those set out in the claims of the '887 and '430 patent] **it seems unlikely that the pre-compression step is essential** to bring an Example 1 type product within the dissolution profile.

(Ex. 22, Supplemental Expert Report of Professor Florence at DDK0006995-DDK0006996 (emphasis added)).

104. In the summary of Professor Florence's Supplemental Expert Report regarding Napp's repeat experiment, Mr. Davidson and Mr. Paradiso failed to inform the Examiner that Professor Florence's comment that the tableting machine was changed also included an important reason for the change. The original tableting machine yielded tablets of poor quality. (*See infra*, ¶¶ 167-182).

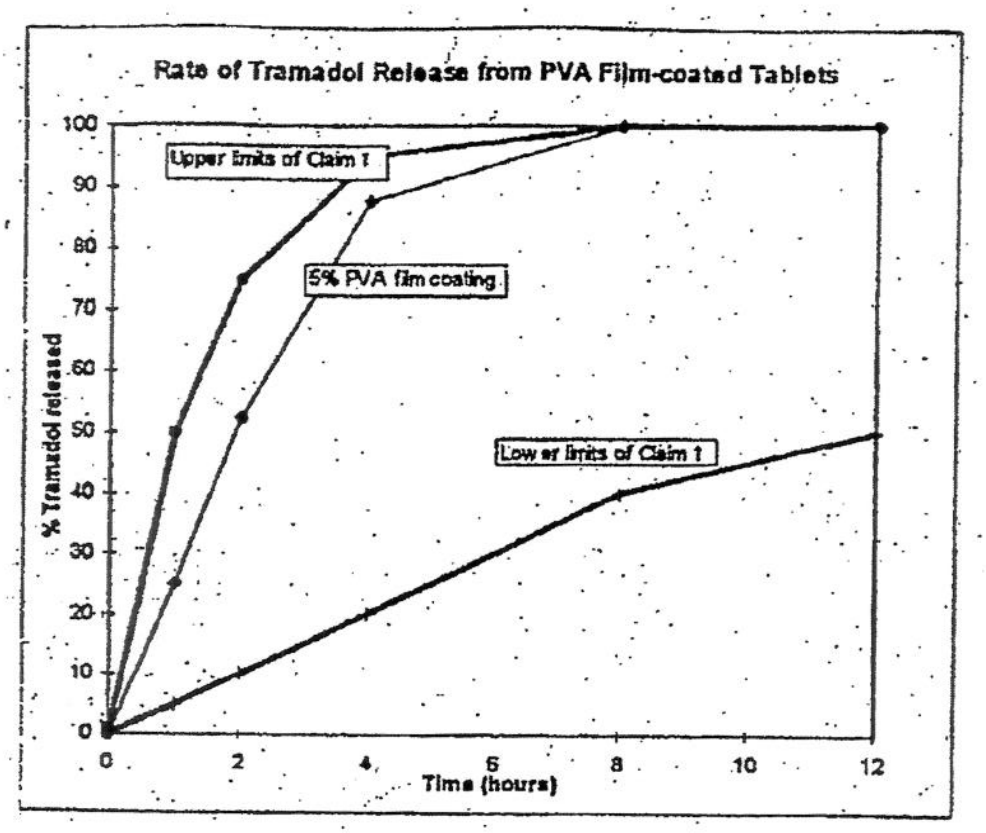
> (I understand that the type of tableting machine was changed **because the apparent quality of tablets produced using the original machine was not good enough**.).

(Ex. 22, Supplemental Expert Report of Professor Florence at DDK0006996 (emphasis added)).

105. In the summary of Dr. Fell's Supplemental Expert Report regarding Napp's repeat experiment, Mr. Davidson and Mr. Paradiso failed to tell the Examiner that Dr. Fell's report

concluded that the results from the Napp repeat experiment "are therefore inconsistent with the pre-litigation experiments conducted by Dr. Malkowska," *i.e.*, her July 26, 1995 and November 19, 1997 declarations. (Ex. 23, Confidential Supplemental Expert's Report of John Tasker Fell ¶ 12).

106. The Supplemental Expert Report of John Tasker Fell provided a graphical depiction of the data generated from the Napp repeat experiment successfully following the Merck reference:



(Ex. 23, Confidential Supplemental Expert's Report of John Tasker Fell at DDK0007020).

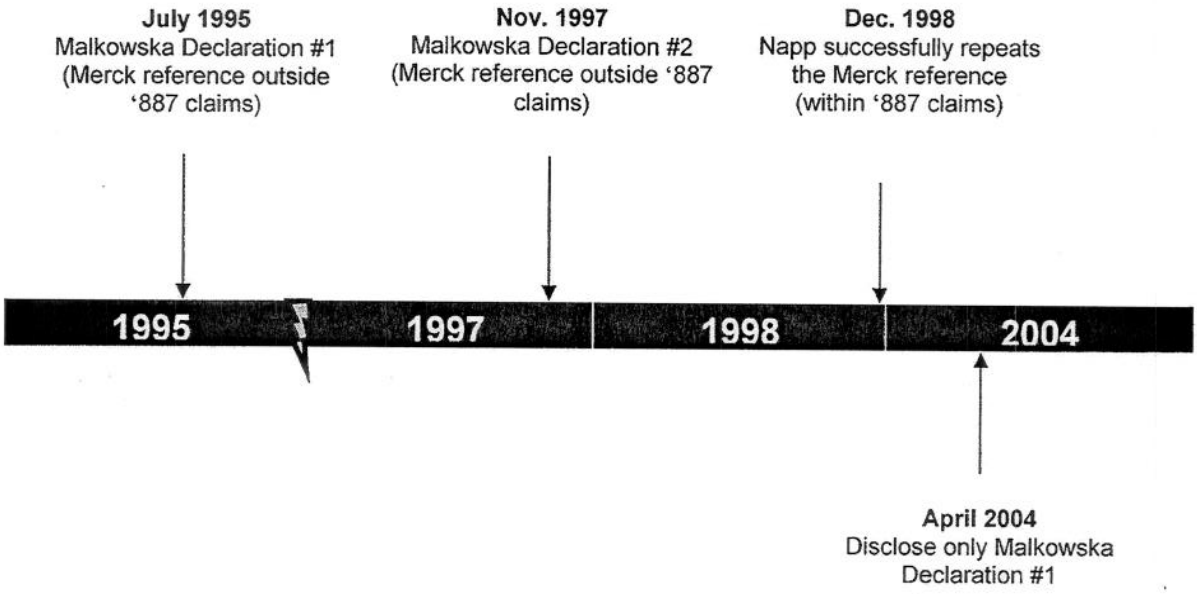
107. Despite evidence showing that Example 1 of the Merck reference provides a formulation within the scope of the '887 claims, Mr. Davidson and Mr. Paradiso concluded that "It is respectfully submitted that the evidence presented does not render the presently claimed invention as anticipated or obvious." (Ex. 24, '887 patent file history at PAR046341).

108. After submission of the March 1, 1999 and March 10, 2000 IDS's, the prosecution history of the '887 patent indicates that Mr. Davidson and Mr. Paradiso discussed them with the Examiner during a personal interview. (Ex. 24, '887 patent file history at PAR046352). There is nothing in the written record, however, that indicates that they discussed the inconsistent data between the Malkowska declarations on the one hand, and the Momberger experiments and the Napp repeat experiments on the other hand.

109. Because the Momberger experiments and the Napp repeat experiments were inconsistent with the Malkowska declarations, they were material and a reasonable Examiner would have considered such information important in deciding whether to allow the application to issue as a patent.

110. A patent applicant can violate the duty of candor by "burying" a reference known to be particularly pertinent in a long list of other less pertinent references. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1183-84 (Fed. Cir. 1995); *Golden Valley Microwave Foods, Inc. v. Weaver Popcorn Co., Inc.*, 24 U.S.P.Q.2d 1801, 1827 (N.D. Ind. 1992). A patent applicant can also violate the duty of candor by not complying with a request by an Examiner. *Paragon Podiatry Lab., Inc. v. KLM Labs., Inc.*, 984 F.2d 1182, 1190-92 (Fed. Cir. 1993).

2. The Napp Repeat Experiments and Other Experiments Were Not Considered By the Examiner During Prosecution of the '430 Patent



111. The official prosecution history of the '430 patent available to me indicates that Mr. Davidson and Mr. Paradiso did not properly bring the Examiner's attention to the Napp repeat experiments. The official Patent Office prosecution history provided to me does not contain any documents which disclose the Napp repeat experiments and/or their results. Paper produced by the Plaintiffs in this action indicate that Mr. Paradiso may have submitted certain IDS's containing information about the Napp repeat experiments from the prosecution of a parent patent but, if so, they do not appear in the official prosecution history. Further, even if they were submitted, they were not considered by the Examiner because the information was not set forth in a 1449 form. (Ex. 13, '430 patent file history at PAR046756-PAR046760). The attorney was told that information contained on a 1449 form would be considered, and in response to that notice, the attorneys submitted 29 pages of 1449 forms, which contained no references to the Napp repeat experiments. (Ex. 13, '430 patent file history at PAR046762-PAR046767). Thus, the Napp repeat experiments were never properly brought to the

Examiner's attention. It should be noted that the Examiner's acknowledgement of information submitted by the attorneys references only information contained in the 1449 forms. (Ex. 13, '430 patent file history at PAR046771-PAR046779).

112. Over 5 years after the Napp repeat experiments, Mr. Davidson and Mr. Paradiso brought only the July 26, 1995 Malkowska declaration to the Examiner's attention. (Ex. 13, '430 patent file history at PAR046780-PAR0046796).

113. Regarding the Merck reference, Mr. Davidson and Mr. Paradiso asserted:

> In fact, it is respectfully submitted that the formulations described in the Bondi [Merck] reference **do not exhibit or enable 12 to 24 hour controlled release dosage forms. This is supported by the enclosed Declaration (Exhibit 1) of Dr. Sandra Malkowska**, which was previously submitted during the prosecution of the parent case, U.S. Patent Application Serial No. 08/241,129, filed May 10, 1994, now U.S. Patent No. 5,591,452 and the corresponding European case, European Patent Application No. 94303128.6, now EP 0 624 366. Ms. Malkowska is one of the named inventors in the presently claimed invention.
>
> Exhibit 1 demonstrates that practical attempts on behalf of inventor Malkowska to produce sustained release compositions in accordance with the teachings of the Bondi reference resulted in a product which released greater than 90% active agent after 2 hours. Tablets were prepared using the formula and process of Example 1 of the Bondi reference, but replacing L-dopa with tramadol hydrochloride. The dissolution rates obtained from Experiments 1 and 2 were as follows:

Table 1

	Product- Experiment 2	Product- Experiment 1
Hour		
1	88	59
2	89	91
3	99	102
4	99	107
5	99	109
6	99	110

> As demonstrated above, the tramadol formulations of the Malkowska declaration resulted in products which resulted in 88 % tramadol released at 1 hour and 91 % tramadol released at 2 hours. Although in-vitro results cannot predict in-vivo results, in-vitro parameters are used as an indication of what formulations would be suitable for further testing. It is respectfully submitted that one skilled in the art would not subject the above formulations to further testing as **there is no indication that such formulations would be suitable for 12 or 24 hour formulations**, based on the in-vitro result of 88 % tramadol released at 1 hour and 91% released at 2 hours for the experimental formulations.
>
> Accordingly, it is respectfully submitted that **the Bondi reference does not exhibit or enable formulations which provide a therapeutic effect for at least 12 or 24 hours as presently claimed**. Therefore, a combination of the Raffa reference with the Bondi reference would not result in a dosage form which provides a therapeutic effect of the active agent for a period of at least about 12 or about 24 hours.

(Ex. 13, '430 patent file history at PAR046789-PAR0046790 (emphasis added not in original (emphasis)).

114. Mr. Davidson and Mr. Paradiso submitted only a copy of the July 26, 1995 Malkowska declaration with the Response Under 37 C.F.R. § 1.116 dated April 21, 2004. (Ex. 13, '430 patent file history at PAR046794-PAR0046796).

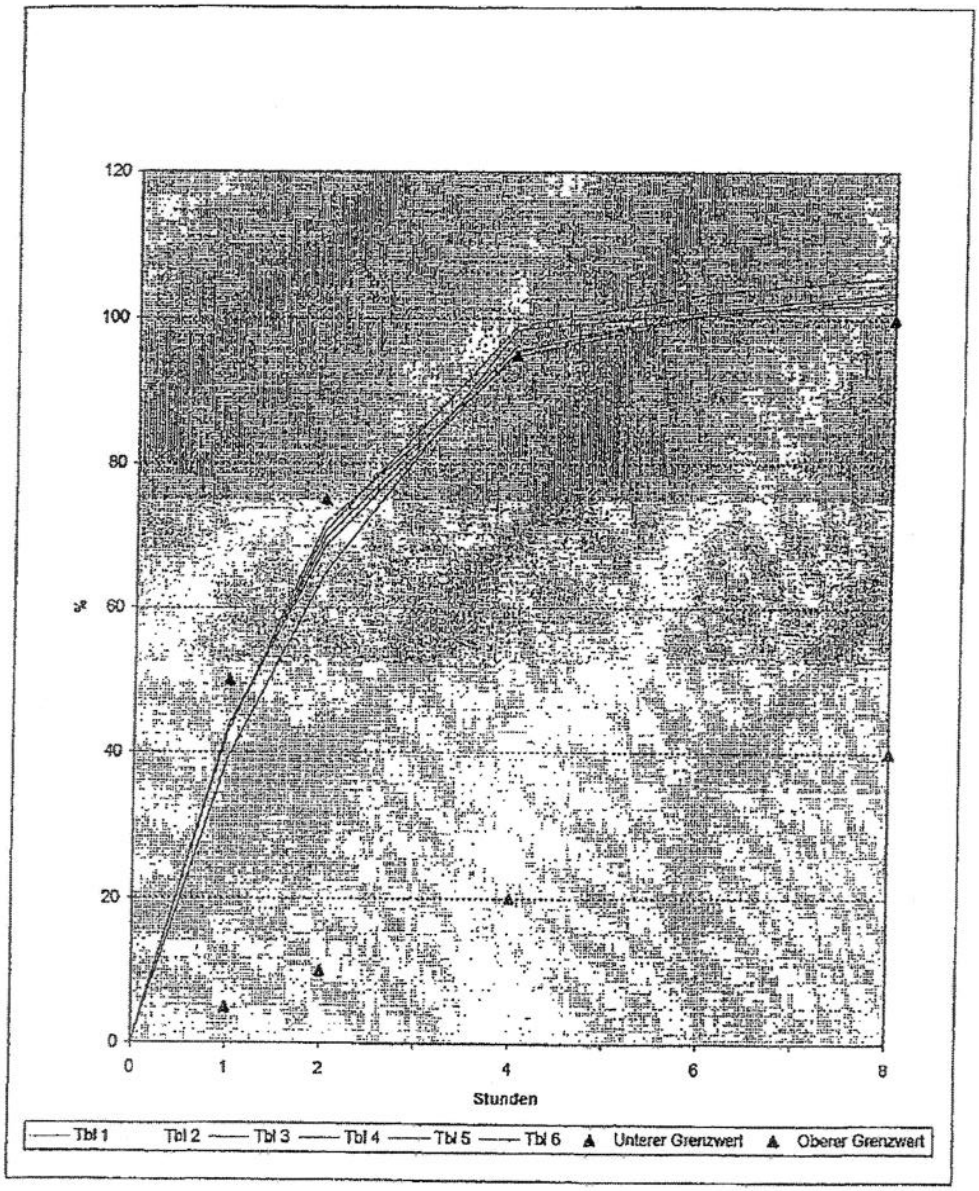
115. Assuming the March 1, 1999 IDS and March 10, 2000 IDS's were submitted to the U.S. Patent Office for consideration in the '430 prosecution (which there is no evidence they were), Mr. Davidson and Mr. Paradiso still failed to direct the Examiner's attention to the Napp repeat experiments, and the conclusion of Napp's own expert that the Merck reference provided a composition falling within the claims.

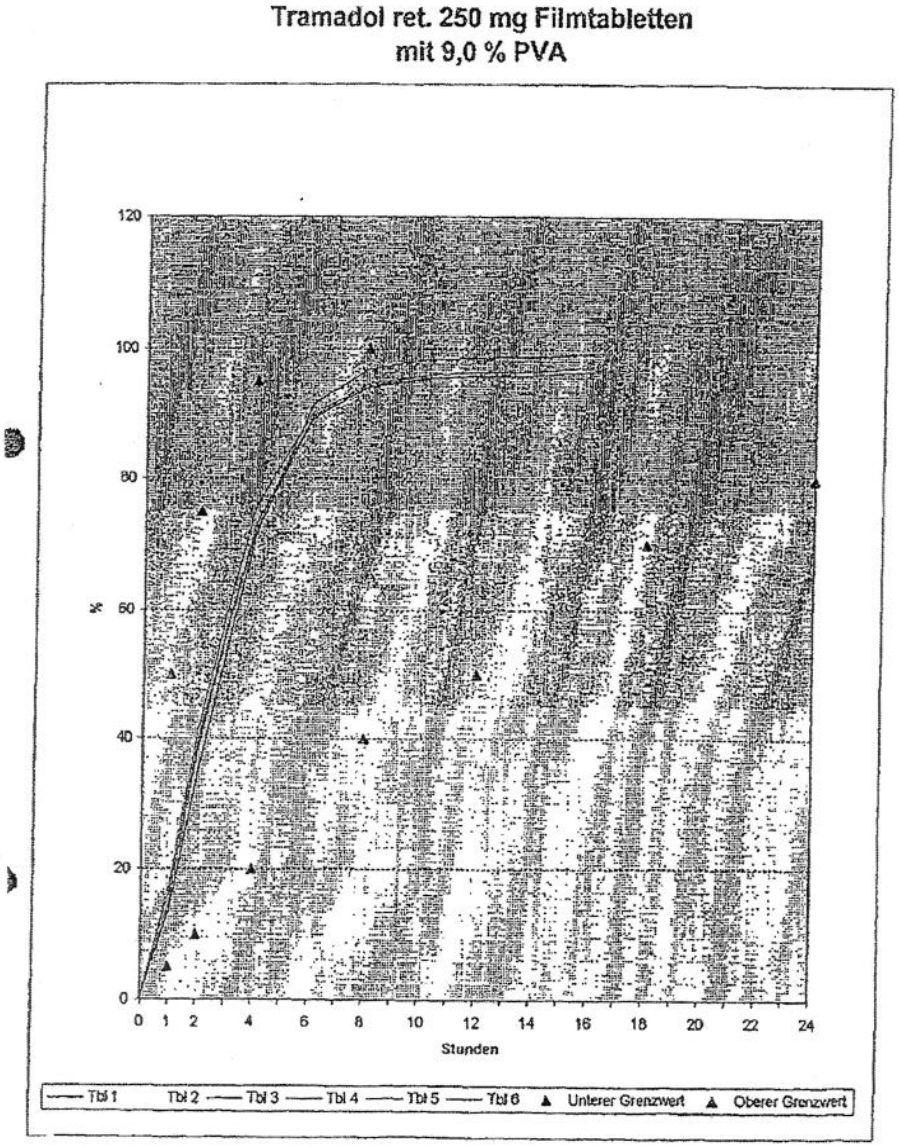
116. Moreover, during prosecution of the '430 patent, Mr. Davidson and Mr. Paradiso failed to effectively bring to the Examiner's attention the Momberger reports.

117. Mr. Davidson and Mr. Paradiso also failed to effectively bring to the Examiner's attention the Posch report, which was disclosed during prosecution of the '887 patent. (Ex. 29, Posch report at PUR0534580-PUR0534584).

118. The graphical depictions of the data from the Posch report are below:

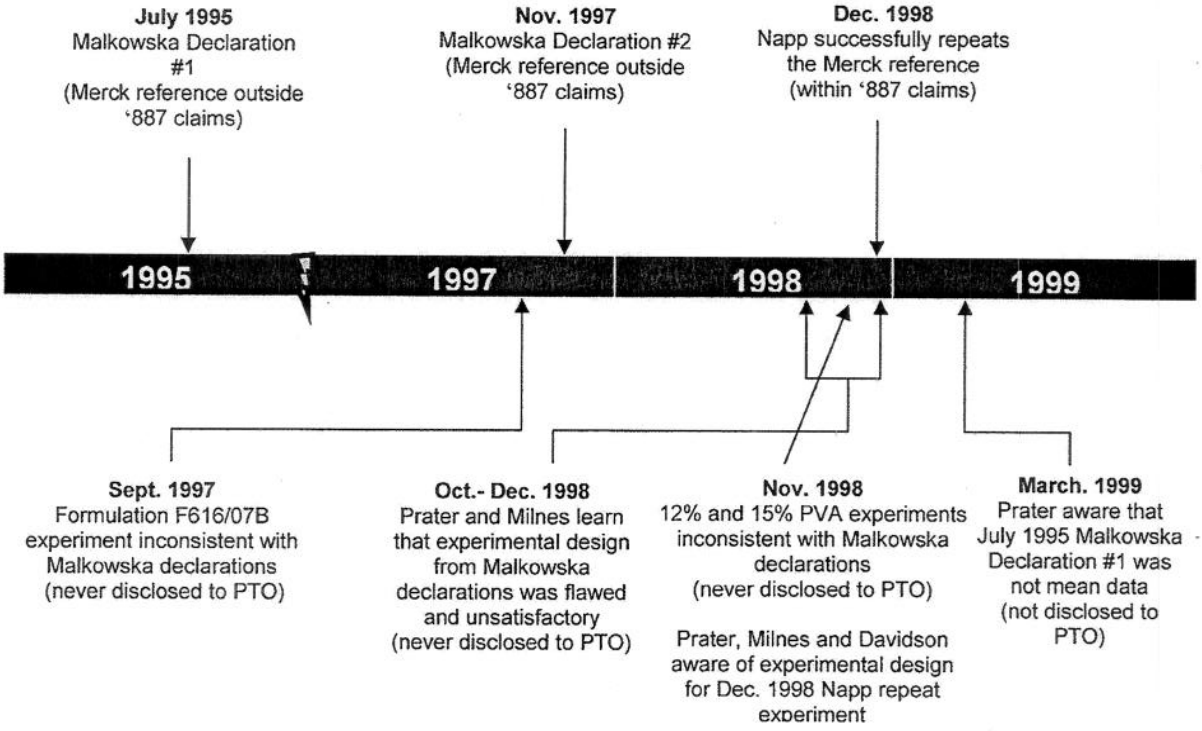
Tramadol ret. 250 mg Filmtabletten
mit 5,2 % PVA





(Ex. 29, Posch report at PUR0534583-PUR0534584).

3. Material Data and Information Unfavorable To the Inventors Was Not Disclosed In Either the '887 File History or the '430 File History



a. Material Information Concerning the Napp Repeat Experiments, Namely (i) the Formulation, (ii) Manufacturing Process, (iii) Testing Conditions and (iv) Raw Analytical Data, Was Not Disclosed

119. I am informed that Mr. Milnes has taken the position that even if the Examiner had known of Professor Florence's and Dr. Fell's supplemental expert reports concerning the Napp repeat experiments, this would not have been enough for him to conclude that the Merck reference anticipated the claims of the patents-in-suit.

120. At Mr. Milnes' deposition, he testified that the information that was disclosed to the U.S. Patent Office during prosecution of the '887 patent concerning the Napp Repeat Experiments was insufficient for an Examiner to consider the relevance.

Q. Would an examiner who has Ms. Malkowska's declaration, would an examiner -- forget an examiner -- would you consider this information [Dr. Fell's supplemental expert report] relevant if you had it before you submitted Ms. Malkowska's declaration?

***

A. The material here, no, I don't think it would be relevant to an examiner.

Q. Why is that?

A. It's too superficial.

Q. The material set forth in John Tasker Fell's supplemental expert report is too superficial to submit to an examiner; is that what your testimony is?

A. In Europe, yes. You have to go – well, forget it.

Q. Why is it too superficial in Europe?

A. You would have to go behind what is disclosed here and see actually how these tests were carried out. There is no -- if you compare this with the declaration of Sandra Malkowska, you'll see that there is no process details. It doesn't go into any detail as to the formulation itself other than saying it's a five percent PVA-coated tablet. You would need further material, I think.

***

A. … What does this document disclose, and I am saying that in order to submit this to the European Patent Office, you would have to go behind the document and gather a lot more material and consider that material and see whether it was relevant or not.

***

Q. Before we broke, we testified that the Tasker Fell report, it didn't have enough information to submit to an examiner in Europe; is that right?

A. I mean, the way you couch that question presupposes that there is a limit above which you have to jump before you submit something to an examiner. I think what I said -- and

> if I didn't say it, then I apologize -- was that I didn't think there would be enough information in there [Dr. Fell's supplemental expert report] for an examiner to be interested in considering it, because there was no disclosure of the formulation work and the testing methods on the face of that particular document that I was -- that I had in hand.
>
> Q. So you would have wanted the examiner to have the formulation work if you were going to be submitting it to the examiner so he can make a determination?
>
> A. Yes…

(Ex. 20, Milnes Tr. 177:17-185:22).

121. In other words, according to Mr. Milnes, in order for an Examiner to determine the materiality of the Napp repeat experiments, an Examiner would have needed to be informed of the (i) formulation; (ii) manufacturing process; and (iii) testing methods. This information was of course available to the inventors and Mr. Milnes and could have been made available to the Patent Office if somehow it would show the Napp repeat experiments were not a "failure" according to Napp's counsel.

122. Mr. Davidson and Mr. Paradiso failed to properly bring to the Examiner's attention the following information relating to the Napp repeat experiments: (i) the formulation; (ii) the manufacturing process; (iii) testing methods; and (iv) raw analytical data.

123. When specifically asked, for example, if the manufacturing process concerning the Napp repeat experiments were disclosed to the U.S. Patent Office, Mr. Milnes testified that such information was indeed not disclosed to the Examiner:

> Q. Setting aside the attachments, do you see a description of the manufacturing process with regards to the supplemental expert report of Professor Florence in the seventeen-page March 10, 2000 information disclosure statement

concerning related foreign litigation [from the '887 patent file history]?

A. No.

***

Q. Is there a description of the manufacturing process set forth with regards to the work submitted in his report, in the March 10, 2000 information disclosure statement concerning related foreign litigation?

A. I can't see it, no.

Q. Do Exhibits 27 and 28 set forth the manufacturing process? Exhibit 27 is the supplemental expert report of Professor Florence and Exhibit 28 is the supplement expert report of John Tasker Fell.

A. No.

Q. That's "No" for both Defendants' Exhibits 27 and 28?

A. Yes.

(Ex. 20, Milnes Tr. 190:7-191:9).

124. Mr. Milnes was aware of the information which he now says would be necessary for an Examiner to determine the materiality of the Napp repeat experiments. By at least November 3, 1998, Mr. Milnes and Mr. Davidson were in possession of Napp's Notice of Facts To Be Proved By Experiment, which described at least the formulation and testing method for the Napp repeat experiments. (Exhibit 21).

125. Mr. Milnes was kept apprised of the *Napp v. Asta* litigation on almost a daily basis and was aware of events in the litigation. (Ex. 20, Milnes Tr. 173:17-174:1).

126. Mr. Milnes understood that the results from the Napp repeat experiment demonstrate that tablets made by Napp based on the Merck reference falls squarely within the

range of release rates set out in the European '366 patent and, therefore, the '887 patent and the '430 patent.

> Q. Were the results [from the Napp repeat experiment] different than the results that were obtained earlier when Ms. Malkowska submitted her declarations during the European opposition?
>
> A. I believe so.
>
> Q. What was different about the results?
>
> A. Well, I believe the experimentation form is different as well, but the results were that the low rate of release was obtained for one of the formulations, at least.

(Ex. 20, Milnes Tr. 137:20-138:6).

127. Mr. Milnes, an agent for the inventors, was intimately involved in the prosecution of the '887 patent and the '430 patent, along with Mr. Davidson. He provided input to office actions and reviewed responses prior to submission to the U.S. Patent Office. (Ex. 20, Milnes Tr. 34:18-38:2). Mr. Milnes is covered under the duty of candor required by 37 C.F.R. § 1.56.

128. Mr. Milnes has approximately 40 years of experience in prosecuting patents. (Ex. 20, Milnes Tr. 17:11-14, 142:3-5). He is aware of the duty of disclosure that exists in the United States concerning the requirement that all material relevant for an Examiner to determine patentability be submitted.

> Q. Are you aware of the duty of disclosure that exists in the United States with regards to submissions to the United States Patent Office?
>
> A. Yes.
>
> Q. What is your understanding of that duty of disclosure?

A. That all material that might be relevant for an examiner in assessing patentability should be submitted to the -- that the applicant, the inventors were aware of should be submitted to the USPTO. I would also like to add that the attorneys who were prosecuting the case were aware of as well.

Q. The duty extends to certainly the attorneys that are prosecuting it and also the inventors; is that right?

A. I believe so.

(Ex. 20, Milnes Tr. 126:19-127:13).

129. Paul M. Cowcher, the Napp employee who supervised the analytical testing in the Napp repeat experiments, testified that for purposes of the Napp repeat experiment, he was supervised and directed by inventor Prater. (Ex. 30, Cowcher Tr. 10:17-11:16; 19:18-24).

130. The analytical testing and data was recorded in notebooks and in an electronic data management system. (Ex. 30, Cowcher Tr. 13:13-17; 14:6-7). It was also videotaped. (Ex. 30, Cowcher Tr. 12:2-7).

131. The table below compares the mean dissolution data from the Napp repeat experiments with claim 1 of the '887 patent and claim 7 of the '430 patent.

Time (Hour)	Mean Data	'887 Patent, Claim 1	'430 Patent, Claim 7
1	25.12%	0-50%	0-50%
2	52.44%	0-75%	0-75%
3	73.54%		
4	87.71%	3-95%	10-95%
5	94.93%		
6	98.29%		

7	99.93%		
8	101.10%	10-100%	35-100%
9	101.70%		
10	102.03%		
11	101.95%		
12	101.87%	20-100%	55-100%
13	101.92%		
14	102.20%		
15	102.28%		
16	102.22%	30-100%	70-100%
17	102.27%		
18	102.19%		
19	102.40%		
20	102.58%		
21	102.35%		
22	102.27%		
23	102.40%		
24	102.34%	50-100%	> 90%
36		> 80%	

b. Material Data and Information Concerning the July 26, 1995 Malkowska Declaration Was Not Disclosed

i. Data From a Single Tablet Was Materially Misrepresented As Mean Data

132. Inventors Prater and Malkowska selectively hid data less favorable to their position of patentability over the Merck reference in the July 26, 1995 Malkowska declaration.

133. Both were aware of their duty of disclosure in connection with prosecution of patents before the U.S. Patent Office. (Ex. 31, Prater Tr. 196:10-197:13; Ex. 19, Malkowska Tr. 41:25-42:10).

134. Inventors Prater and Malkowska provided a memorandum to Mr. Milnes describing the experimentation performed in support of the July 26, 1995 Malkowska declaration (Ex. 32, "March 17, 1995 Prater memorandum").

135. Dr. Prater stated: "I hope this data is adequate to eliminate this citation of prior art." (Ex. 32, March 17, 1995 Prater memorandum at NAPP0037292).

136. For one set of data, formulation batch F523/86 tested in 0.1 N HCl, inventors Prater and Malkowska provided only the data for a single tablet rather than mean data or a complete set of the data obtained. (Ex. 26, Memorandum from Dyer to Prater dated March 17, 1999 ("March 17, 1999 Dyer memorandum") at NAPP0078519-NAP0078519_003; Ex. 32, Prater March 17, 1995 memorandum at NAPP0037295; Ex. 33, Fax from Milnes to Davidson dated May 25, 1995 *compare* DDK0014818 with DDK0014822-DDK0014823).

137. The data provided by inventors Prater and Malkowska for formulation batch F523/86 tested in 0.1 N HCl was from tablet number 6 (of a total of 6 tablets). (Ex. 26, March

17, 1999 Dyer memorandum at NAPP0078519; Ex. 33, Fax from Milnes to Davidson dated May 25, 1995 *compare* DDK0014818 with DDK0014822-DDK0014823).

138. The raw data for the experiment of formulation batch F523/86 tested in 0.1 N HCl shows that the data for tablet number 6 that Dr. Prater and Ms. Malkowska selected to provide was more favorable to their position (of patentability over the Merck reference) than the mean data and data from other tablets tested. (Ex. 17, Fax from Milnes to Davidson dated May 25, 1995 at DDK0014822-DDK0014823).

139. The data for tablet number 6 was the data presented in the July 26, 1995 Malkowska declaration under "Product of Experiment No. 2." (Ex. 17, July 26, 1995 Malkowska declaration at NAPP0342712).

140. Ms. Malkowska represented in her July 26, 1995 declaration that the data presented was from more than one tablet, i.e. mean data. (Ex. 17, July 26, 1995 Malkowska declaration at NAPP0342710).

141. Inventors Prater and Malkowska provided data for a single tablet to the Patent Office, but testified in their depositions that they would only make scientific conclusions or comparisons based on mean data and never from a single tablet. (Ex. 31, Prater Tr. 186:20-187:6, 254:11-255:12, 358:21-359:13, 366:8-9; Ex. 19, Malkowska Tr. 77:2-13, 138:20-23, 140:8-13). For example, Dr. Prater testified:

> A. In the context of any formulation development you would never make a judgment on the basis of one tablet.
>
> Q. But you can make the call based on six tablets?

A. You would make a judgment call on the basis of the totality of all data that you had on a product, not just one dissolution test even.

***

A. There is no way I would make any judgment on the basis of one tablet.

***

A. One tablet is one tablet. It's -- you know, you can't make any scientific conclusion on the basis of one tablet, let alone one time point on one tablet. It's just scientific fact.

(Ex. 31, Prater Tr. 254:11-255:6; 359:3-6).

142. I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that it would be scientifically invalid to analyze data from one tablet as such data has no statistical significance, and that it would be scientifically proper to analyze mean data.

ii. Material Observations and Additional Experiments Performed Were Not Disclosed

143. Inventors Prater and Malkowska, and Mr. Milnes failed to disclose in the July 26, 1995 declaration that during the underlying experimentation, it was observed that the polyvinyl alcohol coating softened in acid medium. (Ex. 32, March 17, 1995 Prater Memorandum at NAPP0037295).

144. Inventor Prater testified that in response to the observation that the polyvinyl alcohol coating softened in acid medium, he would have conducted further experiments to determine the reliability of the results.

Q. Scientifically, if you did an experiment and there was a reported softening of the PVA, would you do further experimentation to determine if your results were robust?

A. Yes.

(Ex. 34, Prater Tr. 125:7-11).

145. I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that a reported observation of softening of the polyvinyl alcohol coating in acid medium would have caused him to question the reliability of the experiments and that he would not have relied on these experiments.

146. Inventors Prater and Malkowska, and Mr. Milnes failed to disclose in the July 26, 1995 declaration that as a result of the observed softening of the polyvinyl alcohol coating softened in acid medium, experiments were performed in water. (Ex. 32, March 17, 1995 Prater Memorandum at NAPP0037295).

147. Inventors Prater and Malkowska, and Mr. Milnes failed to disclose the data from the experiments conducted in water, which was less favorable to their position (of patentability over the Merck reference) than the experiments conducted in acid. (Ex. 32, March 17, 1995 Prater Memorandum at NAPP0037295).

c. Undisclosed Material Data Relating To the November 19, 1997 Malkowska Declaration

i. Material Data That Was Extremely Close To or Overlaps With the Dissolution Range In Claim 1 of the '887 Patent and Claim 7 of the '430 Patent Was Not Disclosed

148. In September 1997, approximately two months before the November 19, 1997 Malkowska declaration, inventors Malkowska and Prater supervised experiments based on the Merck reference that resulted in data that was extremely close to or overlaps with the dissolution ranges in the claims of the '887 patent and the '430 patent.

149. The mean dissolution data from formulation batch F616/07B was as follows:

Time (Hour)	Mean Data	Standard Deviations
1	47.83%	2.30
2	78.93%	3.55
3	92.65%	3.18
4	96.89%	1.60
5	98.19%	1.01
6	98.99%	0.74
7	99.21%	0.65
8	99.79%	0.63
9	93.23%	14.09

(Ex. 35, Formulation Notebook F616 at NAPP0078521_008; Ex. 36, Formulation F616/07B Certificate of Analysis at NAPP0041852-NAPP0041854).[3]

150. Dr. Prater testified that standard deviation values, which reflect variability of data, must be considered when analyzing mean data.

> Q. How would standard deviation values help you understand the results better?
>
> A. … [Y]ou can't just compare means. You need to see the spread of the data as well to see how variable it was.
>
> Q. Why can't you just compare means? Why do you need to see the individual data?

[3] Test TMDOL-06 is the European Paddle Method at 100 rpm in 0.1 M hydrochloric acid at 37°C. (Ex. 31Prater Tr. 222:13-223:12).

A. Because if there is a big difference between the individuals, the means may look very different, but the whole data set may actually overlap.

Q. What is a standard deviation value?

A. It is the variability of the variation of the values. If you got, say, six different values, it's a reflection of the variability of those...

(Ex. 31, Prater Tr. 187:16-188:16).

151. The following table compares the mean range dissolution data, accounting for standard deviation, from formulation batch F616/07B with the ranges disclosed in claim 1 of the '887 patent and claim 7 of the '430 patent.

Time (Hour)	Mean Range Data From F616/07B	'887 Patent, Claim 1	'430 Patent, Claim 7
1	**45.53%** – 50.13%	0-50%	0-50%
2	**75.38%**– 82.48%	0-75%	0-75%
4	**95.29%** – 98.49%	3-95%	10-95%
8	**99.16%**– 100.42%	10-100%	35-100%
12		20-100%	55-100%
16		30-100%	70-100%
24		50-100%	> 90%
36		> 80%	

152. I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that the mean range dissolution data, accounting for standard deviation, from formulation batch F616/07B, is extremely close to or overlaps with the ranges disclosed in claim 1 of the '887

patent and claim 7 of the '430 patent. I also understand that it is the opinion of Dr. Palmieri that this data is closer to the claimed ranges than the data presented in the Malkowska declarations.

153. This data was not disclosed in the November 19, 1997 Malkowska declaration and was not otherwise disclosed to the U.S. Patent Office during prosecution of the '887 patent or the '430 patent.

ii. Data From a Single Tablet That Fell Squarely Within the Dissolution Range of Claim 1 of the '887 Patent Was Not Disclosed

154. Even though Ms. Malkowska had relied on a single tablet in her July 26, 1995 declaration to assert patentability over the Merck reference, *supra*, ¶¶ 132-142, inventors Malkowska and Prater failed to disclose the data from tablet number 3 in the experiments of formulation batch F616/07B.

155. The table below demonstrates that tablet number 3 from formulation batch (F616/07B) falls squarely within claim 1 of the '887 patent.

Time (Hour)	Tablet Number 3 From F616/07B	'887 Patent, Claim 1	'430 Patent, Claim 7
1	43.60%	0-50%	0-50%
2	72.40%	0-75%	0-75%
4	93.80%	3-95%	10-95%
8	98.76%	10-100%	35-100%
12		20-100%	55-100%
16		30-100%	70-100%
24		50-100%	> 90%

36		> 80%	

156. Inventor Malkowska admitted that tablet number 3 from formulation batch (F616/07B) fell squarely within claim 1 of the '887 patent. (Ex. 19, Malkowska Tr. 121:21-122:6).

iii. Material Data Concerning a Higher Coating Level Was Not Disclosed

157. The two Malkowska declarations and the Napp repeat experiments were based on Example 1 of the Merck reference and used a 5% polyvinyl alcohol coating.

158. The Merck reference states that "Generally, the amount of polyvinyl alcohol film coating for the entire drug delivery device (tablet, capsule, suppository & etc.) ranges from 1% to 15% by weight of the entire drug delivery device, preferably from 3% to 10%." (Ex. 16, EP 147,780 at NAPP0045471).

159. The Merck reference further states that "The substance forming the selective film coating membrane is polyvinyl alcohol and its thickness is inversely proportional to the desired rate of release of the drug… The quantity of polyvinyl alcohol necessary for preparing drug forms may vary over a wide range. The quantity used in connection with the active agent in order to be effective in controlling the release of said active agent and rate limiting barrier for drug delivery systems is that quantity necessary to bring about the desired response." (Ex. 16, EP 147,780 at NAPP0045466, NAPP0045470-NAPP0045471).

160. On or about November 3, 1998, inventors Malkowska and Prater supervised the achievement of 12% and 15% polyvinyl alcohol-coated tramadol formulations based on the Merck reference. (Ex. 37, Formulation Notebook F644 at NAPP0406445).

161. Based on a Laboratory Information Management System ("LIMS") data code assigned to this formulation, it appears to have been tested. (Ex. 37, Formulation Notebook F644 at NAPP0406445).

162. I understand that Plaintiffs have not produced data from these experiments in this litigation and are withholding the data on the basis of privilege.

163. The formulations with 12% and 15% polyvinyl alcohol coat based on the Merck reference and its respective data were not disclosed to the U.S. Patent Office during prosecution of the '887 patent or the '430 patent.

164. If this data was inconsistent with the arguments that were being presented in support of patentability during the prosecution of the '887 patent or the '430 patent, the inventors had a duty to submit it to the Patent Office. The Patent Office has procedures for handling the submission of confidential information, and if such information is not material to patentability, it can be expunged pursuant to a petition by the applicant once the prosecution of the involved patent application is completed. MPEP § 724.04.

165. During the European '366 patent opposition proceeding, Asta's expert, Dr. Momberger, demonstrated that formulations with 12.5% and 15% polyvinyl alcohol coatings made following the Merck reference fell within the claims of the '887 patent, *supra* ¶¶ 86-94.

166. I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that he would have expected the 12.5% and 15% polyvinyl alcohol coating formulations based on the Merck reference to fall within the claims of the '887 patent and the '430 patent.

d. Undisclosed Material Information Relating To the Two Malkowska Declarations

i. Material Information Concerning Tablet Quality That Could Have Been Remedied By a Change In Machine Was Not Disclosed

167. Inventors Malkowska and Prater, and in-house patent agent Mr. Milnes failed to disclose to the U.S. Patent Office material information concerning the poor quality of the tablets used in the experiments underlying the two Malkowska declarations.

168. During the experimentation concerning the Merck reference, inventors Malkowska and Prater, and Mr. Milnes became aware that the tablet powder blend used to make the tablets exhibited "poor" flow characteristics. (Ex. 32, March 17, 1995 Prater memorandum at NAPP0037294; Memorandum from S. Malkowska to R. Bates and R. Milnes dated October 29, 1997 (Ex. 38, ("October 29, 1997 Malkowska memorandum") at NAPP0078520_002).

169. The "poorly" flowing blend was compressed using a gravity fed Kilian rotary tablet press, which Dr. Prater testified relies on gravity to move the powder blend through the machine. (Ex. 31, Prater Tr. 213:8-13).

170. Napp concluded that the use of the gravity fed Kilian machine for the "poorly" flowing blend resulted in a "wide variation in tablet weight." (Ex. 38, October 29, 1997 Malkowska memorandum at NAPP0078520_002; *see also* Ex. 32, March 17, 1995 Prater

memorandum at NAPP0037294 (comparing average tablet weight of 340 mg to theoretical tablet weight of 352 mg)).

171. Inventors Prater and Malkowska appreciated that a different type of tableting machine—one that force feeds the powder blend through the machine, such as a Betapress—can help remedy issues of "poor" flow relating to formulations based on the Merck reference. Inventors Prater and Malkowska appreciated this by at least October 1998, when a scientist that they supervised stated "[t]he Betapress will be used for compression as the powder blend did not flow in previous experiments and the powered feeder of this machine may help here." (Ex. 37, Formulation Notebook F644 at NAPP0406436).

172. I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that in the 1990's, one of ordinary skill would have known that a gravity fed tableting machine, such as a Kilian machine, would have been inappropriate for a poorly flowing material intended for tablet compression and that a force fed machine would have been appropriate for such material.

173. Inventors Prater and Malkowska further appreciated the disadvantage in using the gravity fed Kilian machine in December 1998 during the Napp repeat experiments where "[a]s predicted on powering up the Kilian the poor flow properties of this particular formulation prohibited the manufacture of satisfactory tablets within the weight specification. Compression was therefore terminated and transferred to a Betapress (using forced feed)." (Memorandum from Dyer to Prater and Brown dated January 8, 1999 (Ex. 39, ("January 8, 1999 Dyer memorandum") at NAPP0078491_002).

174. Inventor Prater testified "the flow of the powder becomes quite critical to achieving uniform tablets. A forced feeder can help with that process [of making powder

flow]..." (Ex. 31, Prater Tr. 213:21-214-24). He further testified that poor flow characteristics can possibly "make the tablets more variable." (Ex. 31, Prater Tr. 215:15-20).

175. Inventor Prater further testified that it would be "a reasonable thing to try" a forced fed Betapress if aware that a powder blend was not flowing properly. (Ex. 40, Prater Tr. 337:7-25).

176. Inventors Prater and Malkowska had a forced fed Betapress at its disposal at Napp during the experimentation concerning the Merck reference. (Ex. 40, Prater Tr. 348:13-16).

177. In certain instances, the scientist supervised by inventors Malkowska and Prater was instructed not to conduct certain experiments to avoid the production of documents with "unacceptable dissolution profile[s]." (Ex. 40, Prater Tr. 369:7-22).

178. Both Malkowska declarations failed to disclose the "poor" flow characteristics and variation in tablet weight. In the experiments underlying the two Malkowska declarations, inventors Malkowska and Prater knowingly used poor quality tablets.

179. The July 26, 1995 Malkowska declaration misstated the average tablet weight as being the theoretical weight of 352 mg when in fact it was significantly less (340 mg). (*Compare* Ex. 32, March 17, 1995 Prater memorandum at NAPP0037294 with Ex. 17, July 26, 1995 Malkowska declaration at NAPP0342710).

180. Mr. Milnes testified that he had input and provided advice on the experimentation concerning the Merck reference that was supervised by inventors Malkowska and Prater. (Ex. 20, Milnes Tr. 115:4-23, 119:119:13-19).

181. Inventors Malkowska and Prater, and Mr. Milnes failed to disclose to the U.S. Patent Office that the two Malkowska declarations used unsatisfactory tablets that could have been made satisfactory by simply changing the tableting machine.

182. During prosecution of the '887 patent, Mr. Davidson and Mr. Paradiso misrepresented Professor Florence's comment regarding the change in tableting machine for the Napp repeat experiments. (Ex. 24, '887 patent file history, Information Disclosure Statement dated March 10, 2000 at PAR04334, fn; *see supra*, 100, 103). In his supplemental expert report, Professor Florence stated that the tableting machine was changed for an important reason—because the original machine yielded tablets of poor quality.

> "(I understand that the type of tableting machine was changed **because the apparent quality of tablets produced using the original machine was not good enough**.)"

(Ex. 22, Supplemental Expert Report of Professor Florence at DDK0006996 (emphasis added)).

ii. Material Information Concerning Coating Quality That Could Have Been Remedied By a Change In Condition Was Not Disclosed

183. Inventors Malkowska and Prater, and Mr. Milnes failed to disclose to the U.S. Patent Office material information concerning the quality of the coating used in the formulations for the experiments underlying the two Malkowska declarations.

184. During the experimentation underlying the Merck reference, inventors Malkowska and Prater, and Mr. Milnes became aware that the coating conditions used resulted in failed experiments.

185. The July 26, 1995 Malkowska declaration used a fluid flow rate (coating spray rate) of 3 g/min. (Ex. 17, July 26, 1995 Malkowska declaration at NAPP0342711).

186. In September 1997, two months prior to the November 19, 1997 Malkowska declaration, experiments supervised by inventors Malkowska and Prater demonstrated that a slower coating spray rate of 2 g/min resulted in a smoother coat. (Ex. 35, Formulation Notebook F616 at NAPP0078521_004; Ex. 36,Formulation F616/07B Certificate of Analysis at NAPP0041853). It was further observed that "sticking" occurred only when the coating spray rate was approximately 3 g/min, but was not observed when the rate was approximately 2 g/min. (*Compare* Ex. 35, Formulation Notebook F616 at NAPP0078521_004 with NAPP0078521_005).

187. Inventor Malkowska testified that she appreciated that this reduction made a difference in the quality of the tablet. (Ex. 19, Malkowska Tr. 172:17-22).

188. Despite observing that a reduction in coating spray rate resulted in a more satisfactory tablet, inventors Malkowska and Prater, and Mr. Milnes agreed to perform the experiment underlying the November 19, 1997 Malkowska declaration using the same coating conditions as the July 26, 1995 Malkowska declaration at the faster coating spray rate of 3 g/min. (Ex. 38, October 29, 1997 Malkowska memorandum at NAPP0078520).

189. By at least December 1998, inventors Malkowska and Prater further appreciated that the previous experiments using the spray rate of 3 g/min "failed" due in part to the observed sticking of the tablets during the coating process. (Ex. 37, Formulation Notebook F644 at NAPP0406447).

190. By at least October 1998, inventors Malkowska and Prater appreciated that the spray rate needed to be reduced to 1.1 g/min to prevent the tablets from sticking during the coating process. (Ex. 37, Formulation Notebook F644 at NAPP0406444).

191. Inventors Prater and Malkowska further appreciated the result of using a higher coating spray rate (a disadvantage to their patenting efforts) in December 1998 during the Napp repeat experiments where a coating spray rate of approximately 1 g/min resulted in a formulation based on the Merck reference that falls squarely within the range of release rates set out in the '887 patent.

192. I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that having observed that a lower coating spray prevented sticking, one of ordinary skill in the 1990's would have utilized the lower coating spray rate to create a better quality coating on the tablets.

193. Inventors Malkowska and Prater, and Mr. Milnes failed to disclose to the U.S. Patent Office that the two Malkowska declarations used unsatisfactory tablets that could have been made satisfactory by simply changing the coating conditions.

194. In my opinion, the observation that a higher spray rate of 3 g/min resulted in failed experiments and that a lower spray rate of 1-2 g/min resulted in a satisfactory coating of the tablets was material information that a reasonable examiner would have considered such information important in deciding whether to allow the application to issue as a patent.

X. Materiality of a Third Malkowska Declaration During Prosecution of the '887 Patent and the '430 Patent

195. During prosecution of the '887 patent and the '430 patent, a third declaration by inventor Malkowska was submitted by attorneys Mr. Davidson and Mr. Paradiso (dated July 26, 1995). (Ex. 17, Malkowska Declaration dated July 26, 1995, NAPP0136781-NAPP0136782).

196. The third Malkowska declaration stated "[D]rugs differ in their physico-chemical, pharmacokinetic and pharmacodynamic properties. As a result, it cannot be predicted with certainty that a given drug can be successfully formulated to arrive at a desired product profile, for example as a 12 hourly sustained release formulation. Most certainly it does not follow that a given drug can be adapted in a known formulation by direct replacement. Thus, drugs **may differ in their solubility in water** or in lipids and they may or may not give rise to metabolites which may or may not be active themselves. These are important factors in the design of a formulation for sustained release, and it becomes impossible to extrapolate from one drug to another (unless they had wholly identical properties)." (Ex. 17, NAPP0136781 (emphasis added)).

197. The third Malkowska declaration further described the water solubilities of tramadol, morphine sulphate and dihydrocodeine tartrate.

198. The third Malkowska declaration did not describe or compare any other properties of tramadol, morphine sulphate or dihydrocodeine tartrate.

199. Further, I have been informed that hydromorphone has the same water solubility as tramadol (1:3). I understand that it is the opinion of Par's formulation expert, Dr. Palmieri, that water solubility is an important factor in formulating a controlled release dose form. I

understand that it is also the opinion of Dr. Palmieri that knowing that hydromorphone and tramadol have the same water solubilities, one of ordinary skill in the 1990's would have expected success in achieving a controlled release dose form of tramadol using a controlled release formulation of hydromorphone.

200. Inventors Malkowska, Leslie and Miller are inventors of U.S. Patent Nos. 4,844,909 ("the '909 patent") and 4,990,341 ("the '341 patent"), which are both entitled "Controlled release hydromorphone composition."

201. The inventors, Mr. Milnes and Mr. Davidson failed to disclose to the Examiner information concerning the water solubility of hydromorphone, which I believe would have been of interest to the Examiner in deciding whether the claimed subject matter was obvious in light of the prior art.

XI. Intent To Deceive the U.S. Patent Office

202. For inequitable conduct to be established, it must be shown that the applicant mislead the Patent Office by withholding material information or by making material misrepresentations. It must be further established that the withholding or misrepresentation was done with an intent to deceive the Patent Office. Direct evidence of intent to deceive is not required and may be inferred from the surrounding circumstances. *Honeywell Intern. Inc. v. U.S.*, 81 Fed. Cl. 514, 577-78 (Fed. Cir. 2008). Intent may be inferred where an applicant knew or should have known that withheld or misrepresented information would be material to the Patent Office's consideration of the patent application. *Id.* In particular, intent "is most often proven by a showing of acts, the natural consequence of which are presumably intended by the actor." *Semiconductor Energy Lab. Co., Ltd. v. Samsung Elec. Co., Ltd.*, 204 F.3d 1368, 1374-

75 (Fed. Cir. 2000) (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995)). An inference of deceptive intent may fairly be drawn in the absence of a credible explanation for the omission or misrepresentation. *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs. Ltd.*, 394 F.3d 1348, 1354 (Fed.Cir.2005).

203. On the record known to me, the natural consequences of the acts of Mr. Davidson and Mr. Paradiso, on behalf of the inventors and Euro-Celtique, and with the approval of Mr. Milnes, appear to have had the effect of deceiving the Patent Office during the examination of the '887 patent and the '430 patent.

EXHIBIT 1

BIOGRAPHY
HARRY F. MANBECK, JR.

Harry F. Manbeck, Jr. is an attorney-at-law and a member of the firm of Rothwell, Figg, Ernst & Manbeck, P.C. The firm and Mr. Manbeck's offices are located at 1425 K Street, N.W., Suite 800, Washington, DC 20005. From March 1990 to May 1992, he was Assistant Secretary of Commerce and Commissioner of Patents and Trademarks of the United States. He was nominated to these offices by President Bush on October 11, 1989 and confirmed by the Senate on March 9, 1990.

Prior to his government service, Mr. Manbeck practiced patent law for over thirty-five years and at the time of his appointment he was General Patent Counsel of the General Electric Company. He joined General Electric in 1949 and advanced to become General Patent Counsel in 1970, which position he held until becoming Commissioner. Prior to joining the General Electric Company, he served in the U.S. Army Signal Corps.

A native of Honesdale, Pennsylvania, Mr. Manbeck graduated with Highest Honors from Lehigh University in 1949 with a B.S. in Electrical Engineering. He received his L.L.B. with Honors from the University of Louisville in 1954. Mr. Manbeck is a member of the District of Columbia, Connecticut, Indiana, Kentucky and Massachusetts bars and is admitted to practice before the Court of Appeals for the Federal Circuit. He is also registered to practice in front of the United States Patent and Trademark Office.

Mr. Manbeck has served as Chairman of the Patent, Trademark and Copyright Section of the American Bar Association; President of the Association of Corporate Patent Counsel; a Director of the Intellectual Property Owners, Inc.; and a Director of the Bar Association of the Court of Appeals for the Federal Circuit. He is also a member of the American Intellectual Property Law Association and the Connecticut Patent Law Association. In 1984 Mr. Manbeck was awarded the Whitney North Seymour Medal of the American Arbitration Association for contributions made to the process of arbitration in the United States.

Mr. Manbeck is married to the former Julia P. McCarthy and they reside in McLean, Virginia.

EXHIBIT 2

PUBLICATIONS AUTHORED BY
Harry F. Manbeck, Jr.

1. "Voluntary Arbitration of Patent Disputes - The Background to 35 U.S.C. 294", AIPLA Quarterly J. #4, pp. 268-273, Fall 1983.

2. "Entering Our Third Century", Keynote Address Before the American Bar Association Section of Patent, Trademark and Copyright Law, Chicago, Illinois, August 4, 1990, 72 JPOS 1177 (1990).

3. "The Evolution and Issue of New Rule 56", 20 AIPLA Quarterly J., #3 & 4, pp. 137-144, Fall 1992.

4. "The Federal Circuit - First Ten Years of Patentability Decisions", 14 George Mason Univ. L.R. 499 (1992).

5. "Key License Clauses for Technology License Agreements", Technology Licensing 1988, Course Handbook, Series #245, Practising Law Institute, Patents, Copyrights, Trademarks and Literary Property.

6. Author and Presenter, "Current Developments in U.S. and International Law & Policy", Hatsumei Kyokai (Japan Institute of Invention and Innovation) (Tokyo, Japan; March 8, 1993).

7. Co-Author with C. Chalsen and M. Murray, "A Report on the Recommendations of the Advisory Commission on Patent Law Reform", Selected Legal Papers, American Intellectual Property Law Association, Vol. X, No. 2, pp. 3-20 (January 1993).

8. Co-Author and Co-Presenter with C. Chalsen, "A Report on the Advisory Commission on Patent Law Reform", Chizaiken (Japan Institute of Intellectual Property) (Tokyo, Japan; September 16, 1992).

9. Co-Author and Co-Presenter with C. Chalsen, "Techniques for Obtaining a Strong U.S. Patent", Japanese Group of A.I.P.P.I.; Presented: Tokyo, Japan, September 18, 1992, Published: Journal of the Japanese Group A.I.P.P.I., Vol. 38, No. 1, pp. 16-22 (January 1993).

10. Co-Author with C. Chalsen and M. Murray; and Co-Presenter, "Effective Handling of Jury Trials in Patent Cases", Presented: Tokyo, Japan; September 18, 1992, Published: Journal of the Japanese Group A.I.P.P.I., Vol. 37, Nos. 9-10, pp. 12-18 (September - October 1992).

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CHAMBERS OF
SUE L. ROBINSON
CHIEF JUDGE

LOCKBOX 31
844 KING STREET
U.S.COURTHOUSE
WILMINGTON, DELAWARE 19801

Guidelines: Legal Expert Testimony in Patent Cases

In all patent jury trials, the court shows the video "An Introduction to the Patent System" to the jurors in connection with its preliminary jury instructions. The 18 minute video is distributed by the Federal Judicial Center and provides jurors with an overview of patent rights in the United States, patent office procedure and the contents of a patent. Thus, expert testimony from attorneys regarding patent practice and procedure is not required and will not be permitted except in the case of extraordinary circumstances.

"Expert" legal testimony (as opposed to technical testimony) on such substantive issues as invalidity (by anticipation, obviousness, on-sale bar, prior conception, etc.) and claim construction and infringement, generally is not admitted, as descriptions of the law and instructions on the law are matters for the court.

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ONDEO NALCO COMPANY, a Delaware Corporation,	)	
Plaintiff,	)	
v.	)	Civil Action No. 01-537-SLR
EKA CHEMICALS, INC., a Delaware Corporation,	)	
Defendant.	)	

Robert W. Whetzel, Esquire and Steven J. Fineman, Esquire of Richards, Layton & Finger, P.A., Wilmington, Delaware. Counsel for Plaintiff. Of Counsel: Michael Dockterman, Esquire, John S. Letchinger, Esquire, Heather A. Boice, Esquire and Jonathan A. Harris, Esquire of Wildman, Harrold, Allen & Dixon, Chicago, Illinois.

Josy W. Ingersoll, Esquire of Young, Conaway, Stargatt & Taylor, L.P., Wilmington, Delaware. Counsel for Eka. Of Counsel: Richard L. DeLucia, Esquire and Michael D. Loughnane, Esquire of Kenyon & Kenyon, New York, New York.

MEMORANDUM OPINION

Dated: March 21, 2003
Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

On August 10, 2001, plaintiff ONDEO Nalco Company ("Nalco") filed this action against defendant Eka Chemicals, Inc. ("Eka") seeking a declaratory judgment that its 8692 product does not infringe U.S. Patent Nos. 4,385,961 ("the '961 patent"), 4,388,150 ("the '150 patent"), or 5,603,805 ("the '805 patent"), owned by Eka. (D.I. 1) On October 5, 2001, Eka answered and counterclaimed with allegations of infringement and willful infringement of the '150 and '805 patents. (D.I. 15) Nalco subsequently answered Eka's counterclaims and asserted a number of affirmative defenses. (D.I. 81) This court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a).

Presently before the court are various motions. For the reasons that follow: Nalco's motion for ruling on claim construction (D.I. 161) is denied as moot; Eka's motion for partial summary judgment of infringement (D.I. 166) is granted; Eka's motion for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent (D.I. 154) is denied; Eka's motion to strike Nalco's patent law expert's report (D.I. 141) is granted; Eka's motion for summary judgment of no inequitable conduct (D.I. 157) is denied; and Nalco's motion for summary judgment (D.I. 162) is granted in part and denied in part.

II. BACKGROUND

A. The Parties

Eka is a Delaware corporation and the assignee of the '961 patent entitled "Papermaking." Eka is also the assignee of the '150 and '805 patents entitled "Papermaking and Products Made Thereby" and "Silica Sols and Use of the Sols," respectively. Utilizing the technologies of the '961, '150, and '805 patents, Eka has developed papermaking systems and manufactures and sells chemicals used in the papermaking process.

Nalco is a Delaware corporation that also manufactures chemicals for use in the papermaking industry. One of the products Nalco manufactures is its 8692 product, the accused product. This product has been offered for sale in the United States since 1998.

B. The Technologies

The technologies at issue in this case relate to processes of papermaking and the chemicals used in this process. The '805 patent is directed to silica sols and processes using silica sols in the production of paper for improved retention of additives and fines in the paper, as well as improved dewatering in the production process. The '961 and '150 patents are directed to processes of making paper using a binder comprised of cationic starch and colloidal silicic acid, resulting in increased strength and improved levels of retention of additives and fines in the paper.

III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted).

If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient

for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Nalco's Motion for Ruling on Claim Construction

Given the court's claim construction order dated March 21, 2003, Nalco's motion for ruling on claim construction is denied as moot.

B. Eka's Motion for Partial Summary Judgment of Infringement

Eka moves for partial summary judgment that 20 specific sales of Nalco's 8692 product literally infringed claim 3 of the '805 patent. (D.I. 167) Claim 3 is dependent on claim 1 and claims:

> 1. Silica sols having an S-value within the range from 15 to 40 percent comprising anionic silica particles, said silica particles being non-aluminum modified, and having a specific surface area within the range of from 300 to 700 m^2/g.
>
> 3. The silica sols of claim 1 wherein the sol has an S-value within the range of from 15 to 35 percent.

According to the parties, "the only issues in dispute are whether the particles in Nalco's 8692 product are silica particles and, if so, whether the surface area for the silica particles corrected for boron falls within the claimed range when the Nalco 8692 product is sold and/or used." (D.I. 167 at 22)

In its claim construction order, the court construed the term "silica particles" in the '805 patent as "particles of SiO_2, which may include other elements, compounds or substances as well." The term "non-aluminum modified" was construed to mean silica particles that "have not been surface modified with aluminum." Under this construction, Nalco's 8692 product literally infringes the "silica particles" limitation of claim 3 of the '805 patent.

Eka goes on to argue that under the proper surface area measurement techniques, i.e., the Sears method, the surface area of the 8692 product likewise falls within the required range of claim 3. Both parties agree that the surface area measurements must be corrected to account for the presence of boron in the liquid phase of the silica sols in accordance with the Sears method. The parties, however, differ in the amount of correction that must be made. Eka's expert states that a downward correction of 191 m^2/g should be made. (D.I. 168 at A60) Nalco's expert states that the correction should only be 55 m^2/g. (D.I. 169 at A315) Eka argues that even accepting the lower

correction figure offered by Nalco, it is undisputed from Nalco's own surface area and sales data that it sold infringing products on at least 20 occasions. (D.I. 169 at A629)

Nalco does not dispute the surface area data or the sales data for these specific products. The court, after viewing the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion, concludes that the 20 sales identified by Eka were infringing sales; therefore, Eka's motion for summary judgment shall be granted on this issue.

C. Eka's Motion for Summary Judgment That Sales of its BMA-0 Product Do Not Invalidate the '805 Patent

Eka moves for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent, presumably under 35 U.S.C. § 102(b).[1] (D.I. 155) The thrust of Eka's argument is that claim 3 of the '805 patent requires a silica sol with an S-value of 40% or less and Nalco has not shown any evidence that the BMA-0 product sold before 1992 had an S-value in this range.

Reviewing the record submitted, it is undisputed that the BMA-0 product meets all the limitations of claim 3 of the '805 patent other than the S-value range. Eka directs the court to

[1]In its brief, Eka does not argue validity with respect to any specific statutory provision. Since its brief only discusses the sale of its BMA-0 product as non-invalidating, the court assumes Eka is referring to the on-sale bar of § 102(b).

pre-1992 documents which report S-values for the BMA-0 product from 50% to 90%, depending on how the product was made. Nalco relies on a May 1992 document reporting S-values for BMA-0 of 31% and 47%, the former being within the claimed range of 15% to 35%, and asserts that Eka has not produced all relevant documents in this regard.

The court concludes that Eka has failed to carry its burden of proof on this issue. The document relied on by Nalco to show that the BMA-0 product had an S-value of 31% creates a genuine issue of material fact appropriately left for a jury to resolve. The court further concludes that Nalco has failed to demonstrate that Eka's production was so deficient as to warrant a negative inference. As such, Nalco's request that a negative inference be drawn is denied.

D. Eka's Motion to Strike Nalco's Patent Law Expert's Report

Eka moves to strike the expert report of Gerald H. Bjorge, Esquire, on the grounds that it offers legal analysis and opinion which is contrary to this court's standing guidelines on the appropriate scope of patent law expert testimony. (D.I. 142) Eka contends that Mr. Bjorge, a patent attorney, is not a technical expert in the relevant field and cannot provide expert testimony on any aspect of papermaking or papermaking chemistry. In his expert report, Mr. Bjorge "walks through" the file history

of the '805 patent and opines as to how the United States Patent and Trademark Office would have responded had certain prior art been disclosed to it during the prosecution of the '805 patent.

Having reviewed the report, the court concludes that the content exceeds the permissible scope of a patent law expert's testimony. Therefore, the report and testimony based on said report is stricken.

E. Eka's Motion for Summary Judgment of No Inequitable Conduct

Eka moves the court for summary judgment of no inequitable conduct in the procurement of the '805 patent. (D.I. 158) In support of its motion, Eka contends that Nalco never pled the four inequitable conduct claims it raised for the first time in Mr. Bjorge's expert report. Rather, the only inequitable conduct charges in the pleadings are those found in the first amended complaint. Since Nalco chose not to include in its pleadings any of the allegations of inequitable conduct now raised in its expert report, it should be barred from raising these claims at trial.

Nalco argues that it pled the affirmative defense of inequitable conduct in its answer and since Eka failed to seek a more definite statement of the charges until now, it has waived its objection. The proper remedy for insufficient pleading is a Rule 12(f) motion to strike or a Rule 12(e) motion for a more definite statement. Nalco contends that had either of these

motions been made by Eka, the pleading could have been cured.

The court agrees that the proper vehicle for curing pleading deficiencies is by a motion for a more definite statement pursuant to Fed. R. Civ. P. 12(e) or by a motion to strike pursuant to Fed. R. Civ. P. 12(f). See EMC Corp. v. Storage Tech. Corp., 921 F. Supp. 1261 (D. Del. 1996). In the absence of such a motion, the question becomes whether there has been sufficient notice to the opposing party of the specific inequitable conduct allegations to allow for full and fair discovery of such. In this case, certain of the specific allegations of inequitable conduct are contained only in an expert report now stricken from the record, as would the testimony based on said report. Under the circumstances, Eka's motion for summary judgment is granted as to the four theories addressed in the expert report. The motion is denied, however, as to the inequitable conduct allegations properly pled in the amended complaint.

F. Nalco's Motion for Summary Judgment of Non-infringement and Invalidity

1. Non-infringement

Nalco moves for summary judgment that its 8692 product does not infringe any of the patents in suit either literally or under the doctrine of equivalents. (D.I. 163) With respect to the '805 patent, as noted above, the court adopted a broader construction of the "silica particles" and "silica sols"

limitations than that proposed by Nalco. Under the court's construction, Nalco's 8692 product literally infringes these limitations.

Nalco further contends, however, that its 8692 product does not meet the surface area limitations of claim 3 of the '805 patent. In support of its argument, Nalco asserts that at the time of manufacture, the 8692 product particles have a surface area outside the range of the claim limitation. Furthermore, Nalco argues that there is no evidence of record demonstrating that its customers store the 8692 product long enough to cause a drop in surface area to a range falling within the claim limitations. Not surprisingly, Eka disputes this allegation and points to the report of one of its experts concluding that the majority of sales of the 8692 product fall within the range of the surface area limitation of claim 3 of the '805 patent.

Viewing the underlying facts and all reasonable inferences therefrom in the light most favorable to Eka, as it must on summary judgment, the court concludes that there is a genuine issue of material fact as to whether or not the 8692 product, as manufactured or stored, meets the surface area limitations of claim 3 of the '805 patent. Therefore, Nalco's motion is denied as to this issue.

Nalco also argues that its 8692 product does not meet the "papermaking" limitation of the '150 patent because it does not

itself manufacture paper. Additionally, Nalco argues that it does not indirectly infringe the '150 patent by selling the 8692 product to papermakers since there can be no indirect infringement without proof of direct infringement.

Eka refers to Nalco's own 30(b)(6) discovery information as illustrating that Nalco's customers use the 8692 product in an infringing manner and that, viewing the evidence in a light most favorable to Eka, there is sufficient evidence of record to demonstrate a genuine issue of material fact. The court agrees and declines to grant Nalco's motion on this issue.

Nalco finally argues that the court should grant summary judgment of non-infringement of the patents in suit under the doctrine of equivalents because Eka has not supplied any evidence or theory on equivalents and, furthermore, it is barred by the doctrine of prosecution history estoppel from asserting equivalents with respect to the "non-aluminum modified" limitation in the '805 patent.

Upon review of the evidence of record, the court agrees with Nalco that Eka has failed to provide sufficient evidence to support a theory of infringement under the doctrine of equivalents.[2] Therefore, Nalco's motion of summary judgment of non-infringement under the doctrine of equivalents is granted.

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[2]The court finds an expert's conclusory reference to the phrase "insubstantial difference," without more, is an insufficient doctrine of equivalents analysis.

2. **Invalidity**

a. **Obviousness**

Nalco argues that claim 3 of the '805 patent is obvious in light of U.S. Patent No. 2,750,345 ("the '345 patent").[3] (D.I. 163) The '345 patent discloses an S-value of 40% and claim 3 requires an S-value of between 15% and 35%. Nalco asserts that the claimed range and the range disclosed in the prior art are close enough that a person of ordinary skill in the art would expect the silica sols disclosed in the '805 patent to have the same properties as the silica sols disclosed in the '345 patent. As further support of this position, there is record evidence indicating that fluctuations in S-value of 5% or more do not affect the performance of silica sols in the presence of cationic starch.

Eka counters with the assertion that the '345 patent teaches away from having a low S-value and specifically prefers silica particles in which the degree of aggregations is minimal, i.e., a high S-value. In contrast, the '805 patent expressly teaches that a lower S-value is preferred.

The court concludes that upon viewing the facts and evidence in a light most favorable to Eka, entry of a summary judgment on

---

[3]Nalco argues that claims 1, 2 and 4 are anticipated under 35 U.S.C. § 102(b), however, Eka subsequently stipulated that it would not be asserting claims 1, 2, 4, 6 or 8 against the 8692 product either now or in the future. As such, the court will not address this argument.

the issue of obviousness is not warranted. It is evident that the '345 patent teaches a silica sol with S-values of 40% to 90%, preferably 70% to 90%. ('345 patent, col. 7, ll. 45-50) Furthermore, the '345 patent specifically states that "[i]t is particularly preferred to employ silica sols in which the degree of aggregation is at a minimum" and "[t]he gel content of preferred products is not in excess of an amount equivalent to a percent solids, in the dispersed phase, of 40 per cent..." ('345 patent, col. 3, ll. 45-47; col. 7, ll. 52-55) Both of these statements teach that a higher S-value is preferred. It is equally evident that the '805 patent teaches that silica sols with a high microgel content, i.e., a low S-value of preferably between 15-35%, provide "a substantially improved effect" with respect to retention and dewatering in paper. ('805 patent, col. 1, ll. 51-60)

Given the record, the court finds that there is a genuine issue of material fact as to whether a person of ordinary skill in the art would consider the '805 patent obvious in light of the '345 patent.

b. Enablement

Nalco argues that the '805 patent is invalid for lack of enablement under 35 U.S.C. § 112, ¶ 1. In support of this argument, it provides the expert report of Dr. Robert Pelton. In his report, Dr. Pelton summarily states that in several

experiments done at his request, a colleague was unable to make the silica sols of the '805 invention following the specification.

Eka attacks this argument as inadmissible hearsay since Dr. Pelton apparently did not oversee the experiments and had no idea of how the experiments were done or even if they were done. Furthermore, no experimental data or information regarding the alleged "experiments" was provided so that Eka could test Dr. Pelton's data and opinions.

The court concludes that Dr. Pelton's report regarding enablement is inadequate to support Nalco's enablement defense. Therefore, Nalco's motion is denied in this regard and that part of Dr. Pelton's report and testimony is stricken.

c. Inequitable conduct

Nalco argues that the '805 patent is unenforceable due to Eka's inequitable conduct in procuring the patent. In support of its argument, Nalco relies on a 1996 article authored by two inventors of the '805 patent. As discussed above, however, the allegations of inequitable conduct based on this article were never pled by Nalco and the expert report expounding these theories has been stricken. Therefore, summary judgment of inequitable conduct based on this reference is denied.

V. CONCLUSION

For the reasons stated: Nalco's motion for ruling on claim

construction (D.I. 161) is denied as moot; Eka's motion for partial summary judgment of infringement (D.I. 166) is granted; Eka's motion for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent (D.I. 154) is denied; Eka's motion to strike Nalco's patent law expert's report (D.I. 141) is granted; Eka's motion for summary judgment of no inequitable conduct (D.I. 157) is denied; and Nalco's motion for summary judgment (D.I. 162) is granted in part and denied in part. An appropriate order shall issue.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ONDEO NALCO COMPANY, a Delaware Corporation, Nalco, v. EKA CHEMICALS, INC., a Delaware Corporation, Eka.	)	Civil Action No. 01-537-SLR

O R D E R

At Wilmington, this 21st day of March, 2003, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that:

1. Nalco's motion for ruling on claim construction (D.I. 161) is denied as moot.

2. Eka's motion for partial summary judgment of infringement (D.I. 166) is granted.

3. Eka's motion for summary judgment that sales of its BMA-0 product do not invalidate the '805 patent (D.I. 154) is denied.

4. Eka's motion to strike Nalco's patent law expert's

report (D.I. 141) is granted.

5. Eka's motion for summary judgment of no inequitable conduct (D.I. 157) is denied.

6. Nalco's motion for summary judgment (D.I. 162) is granted in part and denied in part.

Sue L. Robinson
United States District Judge

EXHIBIT D

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

L'OREAL S.A. and COSMAIR, INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 98-424-SLR
REVLON CONSUMER PRODUCTS CORP.; CHARLES REVSON, INC.; ALMAY, INC.,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 24th day of February, 2000, having reviewed the various motions in limine filed by the parties to the above captioned litigation;

IT IS ORDERED that:

1. Henlopen "settlement agreement" (D.I. 317). Plaintiffs move to exclude defendants from introducing any evidence or testimony, or making any argument, concerning L'Oreal's "settlement agreement" with Henlopen Manufacturing Co., Inc. on the grounds that the agreement "was in settlement of a dispute regarding Henlopen's infringement of the French counterpart to the patent in suit" and, therefore, is not admissible to prove the amount of damages that defendants should pay to plaintiffs pursuant to Fed.R.Evid. 408. The court disagrees, as there is no evidence of record demonstrating that the "Henlopen - L'Oreal Agreement," as so captioned, is anything

other than a "license," as so characterized in the very agreement at issue, negotiated in a typical commercial setting where a patentee has notified a competitor of its potential infringement. Such evidence, therefore, is relevant to the determination of a reasonable royalty. With respect to plaintiffs' request that two Revlon documents be admitted with references to the Henlopen agreement redacted, said request is denied as well.

2. **Third party opinions of counsel (D.I. 320).** Plaintiffs move to exclude defendants from introducing before the jury any evidence, testimony or argument regarding third party opinions or statements of counsel on the patent in suit. Defendants have responded that they do not intend to introduce the legal advice received by Henlopen as "factual evidence of invalidity" or as relevant evidence of willfulness. (D.I. 342 at 2) To the extent that plaintiffs seek a broader ruling without identifying any further evidence, the court declines to do more than advise the parties that, before any such evidence is to be introduced through a witness, the offering party must so advise opposing counsel and the court in order to determine the admissibility of such evidence in a focused context.

3. **Revlon opinions of counsel (D.I. 321).** Plaintiffs move to exclude defendants from introducing before the jury any evidence, testimony or arguments regarding opinions rendered by counsel in April 1996 and September 1998 to Revlon on the patent in suit. Based on the discussion in SRI Int'l, Inc. v. Advanced Tech. Labs., Inc., 127 F.3d 1462, 1467-68 (Fed. Cir. 1997), the

court concludes that evidence of legal advice rendered subsequent to the commencement of infringing activity is relevant to the issue of willfulness and should be admitted.

4. **Willfulness-related evidence** (D.I. 323). Defendants move to preclude plaintiffs from offering evidence relating to willful infringement prior to a liability verdict. The motion is denied, as contrary to this court's trial practice.

5. **Patent law expert** (D.I. 325). Defendants move to limit the testimony of plaintiffs' patent law expert to matters of U.S. Patent and Trademark Office practice and procedure. Plaintiffs contend that they do not intend to offer testimony contrary to the court's guidelines, consistent with the motion. The motion, apparently unopposed, is granted. The court notes in this regard, however, that no expert shall be permitted to offer an opinion of law or an opinion as to "the thoroughness of the consideration of those issues" considered by the examiner.

6. **Plaintiffs' expert witness on mascara brush design** (D.I. 326). Defendants move to limit the testimony of John M.B. Ford, offered by plaintiffs as an expert in the field of mascara brush design and manufacture. The motion is granted in part and denied in part. As noted by plaintiffs, Fed.R.Evid. 703 permits a testifying expert to form opinions and draw inferences from any evidence "perceived by or made known to the expert at or before the hearing." Such evidence then is subject to disclosure at trial. The motion is denied, therefore, with respect to any evidence relied upon by Mr. Ford to form those opinions based on

his proven experience and expertise, e.g., as to infringement.[1] The motion is granted, however, with respect to those "opinions" to be offered by Mr. Ford which do not rest upon any experience or expertise claimed by this witness, e.g., the date of invention.

7. Appointment of a neutral interpreter (D.I. 324). Defendants move for appointment of a "neutral" interpreter based on a perceived "personal bias" or "partiality" on the part of the independent, certified court interpreter who has provided interpreting services at ten multi-day depositions of L'Oreal's French speaking witnesses. The court declines on the record presented to preclude the services of said interpreter, Ms. Abreu. In the absence of the parties' agreement as to the retention of one qualified interpreter, the parties shall each hire a qualified interpreter to service their interpretative needs and to serve as a check on the abilities of the opposing parties' interpreter. The court notes in this regard, however, that the trial will be a timed proceeding and any time wasted by the parties' bickering over inconsequential interpretative nuances will be assigned against the offending party.

United States District Judge

[1]The record provided was insufficient for the court to determine at this time whether Mr. Ford in fact has the industry experience to enable him to offer testimony as to the sale and marketing of prior art brushes.

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LUCAS AEROSPACE, LTD., Plaintiff and Counter Defendant,	:	
v.	:	Civil Action No. 93-525-JJF
UNISON INDUSTRIES, L.P., Defendant and Counter Claimant.	:	

O R D E R

WHEREAS, Defendant Unison Industries, L.P. ("Unison") filed Motion in Limine No. 2 to Limit the Testimony by Plaintiff's Patent Law Expert A. Donald Messenheimer (D.I. 269);

WHEREAS, Unison contends that Mr. Messenheimer as a patent law expert should not be permitted to give opinions on the issues of law or the legal significance of the facts;

WHEREAS, Lucas Aerospace, Ltd. ("Lucas"), by way of response contends that Mr. Messenheimer's testimony will provide the jury and the Court with the benefit of his specialized knowledge regarding the practice of obtaining a patent and the procedures followed in the application which resulted in the patents at issue;

WHEREAS, Lucas further contends that any objections to particular questions are more appropriately raised during the course of trial at the time Mr. Messenheimer's testimony is elicited before the jury;

WHEREAS, the Court finds that Mr. Messenheimer is offered as a witness on practice and procedure in the Patent and Trademark Office as indicated by Lucas in their briefing;

WHEREAS, the Court finds that "patent law experts" are permitted to testify about Patent Office practice and procedure but not to draw inferences or make statements or conclusions about the patent law of the case;

NOW THEREFORE, IT IS HEREBY ORDERED this 9 day of March, 1995, that Unison's Motion in Limine No. 2 to Limit the Testimony by Plaintiff's Patent Law Expert A. Donald Messenheimer is GRANTED, and Mr. Messenheimer is limited to factual recitations concerning practice and procedure in the Patent and Trademark Office.

Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

THORN EMI NORTH AMERICA, INC., Plaintiff, v. MICRON TECHNOLOGY, INC., and Defendants. MICRON SEMICONDUCTOR, INC., Counterclaimant, v. THORN EMI NORTH AMERICA, INC., Counterdefendant.	)	Civil Action No. 92-673 (RRM)

Federal Courtroom
No. 4 - 2nd Floor
U.S. Courthouse
844 King Street
Wilmington, Delaware

Tuesday, November 23, 1993
1:15 p.m.

BEFORE: HONORABLE RODERICK R. McKELVIE
United States District Court Judge

Pretrial Conference

WILCOX & FETZER
1330 King Street - Wilmington, Delaware 19801
(302) 655-0477

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The other day Judge Niece had to walk through with me some of the other mistakes that she thought were in there, most of them had to do with issues of law versus issues of fact. And I'm going to look through them.

And there may never be a solution in life about this, but I do think what ends up happening is people compromise by building a camel in the instructions and nobody pays much attention to it. And I spend an hour up here reading to the jury stuff that just doesn't make a whole lot of sense, but we will keep working on it and we'll see if we can improve it.

Okay. Expert witness. Let me talk for a minute about patent office practice and procedure on expert witnesses on law. As people know, the other judges in this district and I have adopted a general practice of stating that we don't allow opinions on issues of law, that we do allow parties to call expert witnesses to testify on patent office practice and procedure. And while I know that certain lawyers think that's an exception you can drive a truck through and you can offer all kinds of opinion on law, in any event I try to stop

that truck from passing through this courtroom. And I like to try to be as clear as I can be about what my limitations are so there is no embarrassment during the trial.

And if you put a witness on and he's on and off in three minutes because you don't want to here it, I won't let him talk to the jury about it. I believe witnesses, expert witnesses on patent office practice and procedure tend to be helpful in the sense that you can put them on the stand, they can take the file and they can walk the jury through the file to explain to them what has happened in the patent office and what the context is for what's happening.

And maybe that's helpful in part because the Court's limit discovery and testimony on patent office practice and procedure. For example, we can't have a patent examiner here. So to me it's almost an evidentiary aid to bring an expert in, hand him a document and use a witness on the stand to walk the jury through a paper that's otherwise admitted into evidence, but they may not understand it other than through argument by counsel.

Now testimony on patent office practice and procedure to me means patent office practice and procedure, but not opinions on what I think are questions of law that arise on what the significance may be on certain things that took place at the patent office.

So in connection with Mr. Bjorge, I can tell you that it looks like he's going to be testifying to some things that I wouldn't normally allow an expert to testify to, and I suggest that people look back again at the experts on questions of law and see whether they're going to testify on questions of law or practice and procedure.

Okay. So now I have some spots tabbed in the pretrial order that I'm happy to talk to, but I have a feeling as soon as I open them up things are going to start to degenerate. I will pick some easy ones first.

Procedure for notifying the other side as to who is going to testify, that's an easy one, isn't it? Two parts to that. You all want notice on who is going to testify next, and I don't want dead time. And in the trial we just finished we did have a good bit of dead time; looks like

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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F. HOFFMAN-LA ROCHE, LTD., Plaintiff, v. IGEN INTERNATIONAL, INC., ORGANON TEKNIKA CORPORATION, and ORGANON TEKNIKA B.V., Defendants.	:	Civil Action
	:	No. 98-318-JJF

- - -

Wilmington, Delaware
Tuesday, October 24, 2000
9:30 a.m.

- - -

BEFORE: HONORABLE JOSEPH J. FARNAN, JR., U.S.D.C.J.

APPEARANCES:

RICHARD K. HERRMANN, ESQ.
Blank Rome Comisky & McCauley LLP
-and-
DANIEL A. BOEHNEN, ESQ., and
GRANTLAND G. DRUTCHAS, ESQ.
McDonnell Boehnen Hulbert & Berghoff
(Chicago, Illinois)

Counsel for Plaintiff

JACK B. BLUMENFELD, ESQ.,
MARY B. GRAHAM, ESQ.,
MARYELLEN NOREIKA, ESQ.,
KAREN JACOBS LOUDEN, ESQ., and
RICHARD W. ELLIS, ESQ.
Morris, Nichols, Arsht & Tunnell

Counsel for Defendants

MINUSCRIPT WITH WORD INDEX

THE COURT: Give me that number roughly. What would that number be roughly?

MR. BLUMENFELD: I don't know the answer to that. I don't know what the cost number is. I know what the list price is. We can go back and get that information. I think we can work this out.

THE COURT: You have the three categories. If you can't agree, give me the hard numbers on the first two and I will tell you what the kicker is going to be.

MR. BOEHNEN: We have been asked for the cost of goods and haven't been able to get it.

THE COURT: You are going to get it sold. So the application is granted on the principles discussed.

MR. BOEHNEN: Would you direct the defendants to give us their information on the cost of goods sold? We should be getting that for damages anyway.

THE COURT: Yes. He said he is going to do that and I have ordered that.

MR. BLUMENFELD: That information has been provided.

THE COURT: You should be able to get that.

MR. BOEHNEN: Okay, Your Honor. I believe that brings us up to (e) on the next page. The protective order, this is the generic kind of protective order that is normally entered at the outset of a case, both sides have presented

them, and the essential issue I will turn over to Mr. Drutchas. Or maybe you know what your ruling is, have had a chance to read it.

MR. DRUTCHAS: You may be fully aware. Two protective orders, HLR has proposed one that has the same terms for all the parties. The defendants have proposed one that has two tiers for Igen documents, or Igen or HLR documents, and two separate tiers for Organon Teknika documents as to who has access, basically requiring us to be under a protective order that we think isn't equally applied across the board.

THE COURT: It should be a two-tier order. As I understand the presentations, that would work. I don't know what else to tell you.

MR. BOEHNEN: Two tiers equally across the board.

THE COURT: Yes. If you want to have a carveout for something unusual, call me.

MR. BOEHNEN: The next issue, Your Honor, gets into some other expert witnesses. The first one is a patent attorney named John Goolcasian. We submitted his curriculum vitae and they have refused to agree to let him have access under the protective order.

MR. BLUMENFELD: Your Honor, this is a very narrow issue. Mr. Goolcasian is a patent lawyer down in Virginia. And when we got the undertaking, my presumption –

this, by the way, is a Bench trial. This isn't a jury trial. My presumption was that they wanted him –

THE COURT: Patent law expert.

MR. BLUMENFELD: We are the defendant. It is their patent. I said why does he need access to our confidential information? The response I got was, oh, no, he is also going to testify on willfulness. And my understanding of the law on willfulness is that it's the client's state of mind. I don't think Mr. Goolcasian is going to have much to add about the client's state of mind. If Your Honor wants to hear from him, then I guess we can let him see it. When I asked Mr. Boehnen this morning, what is it you want him to see, and he said I want to have him have the ability to see any of the 175,000 pages of documents –

THE COURT: He didn't really say that. You misunderstood him.

MR. BLUMENFELD: It's close enough.

MR. DRUTCHAS: If I can respond, Your Honor. As far as Mr. Goolcasian's testimony goes, there is really two aspects. One, getting to the ultimate trial issue, and whether you want to have his testimony or not is something that we should really be resolving in a motion in limine, not at this stage. We are certainly entitled to have the assistance of an expert such as Mr. Goolcasian assist us with preparing the case and potentially be an expert, assuming

that this Court ultimately –

THE COURT: Not really. If you want assistance in preparing the case, hire him as special litigation counsel. If you want him to come under the rules of an expert witness, you are in a different ballgame. And in this district, when you get into that patent law/expert/et cetera area, we have a very consistent view. And the view is that they are not helpful. And not only do we mostly exclude them on Bench trials, but in jury trials they are so severely limited, I can't figure out why anybody continues to propose them. It's been called the anti-Manbeck, whatever that guy's name is, employment decision, the former Commissioner. But at any given period of time, it started with Chisum, we put him out of here and we have gone through different – I am trying to be helpful to you in a way that makes you understand – he didn't really get to see all the information they have because we don't have a place for him in the expert column.

MR. BOEHNEN: Can I ask, what would the Court's view be of an expert witness on the competency of opinion of counsel? Their defense to willfulness is reliance on opinion of counsel. One of the things they have to show is that it is a competent opinion.

MR. DRUTCHAS: Let me add to that, Your Honor. The Federal Circuit, in a case, In Re Hayes, and

EXHIBIT H

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORNING INCORPORATED, ARTIFICIAL SENSING INSTRUMENTS ASI AG,	:	
Plaintiffs,	:	
v.	:	Civil Action No. 03-633 JJF
SRU BIOSYSTEMS, et al.,	:	
Defendants.	:	

MEMORANDUM AND ORDER

Pending before the Court is Defendants' Motion To Exclude The Expert Report And Testimony Of Corning And ASI's Patent Law Expert, Gerald J. Mossinghoff (D.I. 129). For the reasons discussed, Defendants' Motion will be granted.

PARTIES' CONTENTIONS

By their motion, Defendants contend that Mr. Mossinghoff's report and proposed testimony, while couched as explanations of Patent and Trademark Office ("PTO") practices and procedures, consist primarily of legal opinions on various patent issues, including ultimate issues of law.

Plaintiffs contend that Mr. Mossinghoff's opinions on PTO procedures are relevant and within the proper scope of expert testimony on patent matters.

DISCUSSION

Because Mr. Mossinghoff's report and proposed testimony deal primarily with internal patent office procedures, the Court will grant Defendants' Motion To Exclude The Expert Report And Testimony Of Corning And ASI's Patent Law Expert, Gerald J. Mossinghoff (D.I. 129).

NOW THEREFORE, IT IS HEREBY ORDERED this 5 day of November 2004, that Defendants' Motion To Exclude The Expert Report And Testimony Of Corning And ASI's Patent Law Expert, Gerald J. Mossinghoff (D.I. 129) is **GRANTED**.

Joseph J. Farnan, Jr.
UNITED STATES DISTRICT JUDGE